1		TITLE 77: PUBLIC HEALTH
2		CHAPTER I: DEPARTMENT OF PUBLIC HEALTH
3		SUBCHAPTER d: LABORATORIES AND BLOOD BANKS
4		
5		PART 450
6		ILLINOIS CLINICAL LABORATORIES CODE
7		
8		SUBPART A: GENERAL
9		
10	Section	
11	450.5	Scope and Applicability
12	450.10	Definitions
13	450.20	Permit and License (Certification) Application
14	450.30	Laboratories Covered
15	450.35	Testing Limitations for Exempt, Permit, and Licensed Laboratories (Repealed)
16	450.40	Penalties and Fines
17	450.50	Incorporated and Referenced Materials
18	450.60	Administrative Hearings
19		<u> </u>
20		SUBPART B: DIRECTORS OF CLINICAL LABORATORIES
21		
22	Section	
23	450.210	Qualifications of the Director of a Clinical Laboratory
24	450.220	Operational Participation of the Director
25	450.230	Number of Laboratories Permitted to Operate
26		•
27		SUBPART C: LOCATION, CONSTRUCTION AND SANITATION
28		
29	Section	
30	450.310	Location
31	450.320	Conformance to Local Ordinances
32	450.330	Safety and Sanitation Manual
33		
34		SUBPART D: QUALIFICATIONS OF PERSONNEL
35		
36	Section	
37	450.410	General Supervisor
38	450.420	Testing Personnel Medical Technologist
39	450.430	Cytotechnologist (Repealed)
40	450.440	Technician (Repealed)
41	450.450	Laboratory Assistant (Repealed)
42	450.460	Technical Supervisor
43	450.470	Clinical Consultant

44		
45		SUBPART E: EQUIPMENT
46		
47	Section	
48	450.510	Facilities and Equipment
49	450.520	Preventive Maintenance of Equipment and Instruments
50	450.530	Glassware (Repealed)
51	450.540	Lancets, Needles and Syringes (Repealed)
52	450.550	Electrical Equipment (Repealed)
53	450.560	Photometric and Spectrophotometric Equipment (Repealed)
54	450.570	Analytic Balances and Weights (Repealed)
55		
56		SUBPART F: OUT OF STATE LABORATORIES
57		
58	Section	
59	450.610	Criteria for Licensure
60		
61		SUBPART G: PROFICIENCY SURVEY PROGRAM AND
62		INSPECTION OF FACILITIES
63		
64	Section	
65	450.710	Inspections
66	450.720	Proficiency Survey Program
67	450.730	Western Blot Assay Testing Procedures
68		
69	SUBPAR'	T H: SPECIAL REQUIREMENTS PERTAINING TO BLOOD BANKS (Repealed)
70		
71	Section	
72	450.810	General (Repealed)
73	450.820	Applicability of Other Parts of the Regulations (Repealed)
74	450.830	Donors and Donor Blood/Criteria for Donor Selection (Repealed)
75	450.835	Directed Blood Donations (Repealed)
76	450.840	Donors and Donor Blood/Identification of Donor Blood (Repealed)
77	450.845	Donors and Donor Blood/Storage and Transportation (Repealed)
78	450.848	Preparation of Blood Components (Repealed)
79	450.850	Plasmapheresis (or Plateletpheresis) (Repealed)
80	450.860	Autologous Transfusion (Repealed)
81	450.870	Transfusion Service Records (Repealed)
82		
83		SUBPART I: PROHIBITED PRACTICE
84		
85	Section	
86	450 920	Terms Not to be Used in Names of Laboratories

87 88 89	450.930 450.940 450.950	Prohibitions in Advertising and Announcements Acceptance of Specimens and Reporting of Results Referral of Specimens for Examination to Unlicensed Laboratories						
90								
91 92		SUBPART J: RECORDS AND REPORTS						
93	Section							
94	450.1010							
95								
96		SUBPART K: QUALITY CONTROL						
97	g .:							
98	Section	Deemoneikilities of Director						
99 100	450.1110 450.1120	Responsibilities of Director Reference Materials						
100	450.1120							
101	450.1130	Preventative Corrective Maintenance Program Procedure Manuals						
102	450.1150	Quality Control System Methodologies						
103	450.1155	Cytology						
105	450.1155 Cytology							
106	S	UBPART L: HIV CONTAMINATED BLOOD AND HUMAN TISSUE						
107	۵							
108	Section							
109	450.1200	Handling and Disposal of HIV Contaminated Blood and Human Tissue						
110								
111		SUBPART M: HEALTH SCREENING						
112	- ·							
113	Section							
114	450.1300	Health Screening and Approved Health Screening Tests						
115	450.1310	Protocol for Conducting Health Screening						
116	450.1320	Application for a Class III Permit to Conduct Health Screening (Repealed)						
117	450.1330	Reporting and Notification						
118	450 ADDENII	DIV A Application for Degistration Class I Darmit Class II Darmit and						
119 120	450.APPENI	DIX A Application for Registration, Class I Permit, Class II Permit, and Licensed Laboratory (Repealed)						
120	450.APPENI	V \ 1 /						
122	450.APPENI							
123	+30.711 LIVI	(Repealed)						
124		(Tropodica)						
125	AUTHORIT	Y: Implementing and authorized by the Illinois Clinical Laboratory and Blood						
126	Bank Act [210 ILCS 25].							
127	Ĺ	-						
128	SOURCE: A	Amended November 16, 1970; amended at 2 Ill. Reg., p. 87, effective November 5,						
129	1978; amended at 4 Ill. Reg. 33, p. 224, 225 and 228, effective August 6, 1980; amended at 6 Ill.							

130 131 132 133 134 135	at 8 Ill. Reg. amendment a at 10 Ill. Reg 1988; emerge	fective April 5, 1982; amended at 7 Ill. Reg. 7643, effective June 14, 1983; codification of 19488; amended at 9 Ill. Reg. 20709, effective January 3, 1986; emergency at 10 Ill. Reg. 307, effective January 3, 1986, for a maximum of 150 days; amended 10712, effective June 3, 1986; amended at 12 Ill. Reg. 10018, effective May 27, ency amendment at 12 Ill. Reg. 19518, effective October 28, 1988, for a maximum amended at 13 Ill. Reg. 4285, effective March 21, 1989; amended at 13 Ill. Reg.
136	•	ive July 1, 1989 and September 1, 1989; emergency amendment at 13 Ill. Reg.
137		ive August 14, 1989, for a maximum of 150 days; emergency rule expired Januar
138	*	ended at 14 Ill. Reg. 2360, effective January 26, 1990; amended at 15 Ill. Reg.
139		ive October 18, 1991; amended at 44 Ill. Reg, effective
140	10.2., 011000	
141 142		SUBPART A: GENERAL
143	Section 450.	Scope and Applicability
144		scope and rippincusmiy
145	a)	This Part provides regulatory oversight The major thrust of this regulatory schen
146	,	is to require some form of regulation of all entities, licensed (certified) pursuant
147		42 CFR 493, that perform analysis of human specimens for health assessment o
148		to diagnose, prevent or treat disease. under the following five stage classification
149		scheme:
150		
151		1) Exempt Laboratory;
152		
153		2) Class I Permit Laboratory;
154		
155		3) Class II Permit Laboratory;
156		
157		4) Class III Permit Laboratory;
158		
159		5) Licensed Laboratory.
160		
161	b)	All <u>certified CLIA</u> laboratories will be regulated as one of these five levels of
162		classification as set forth in 42 CFR 493 and described in the State Operations
163		Manual (Appendix C – Survey Procedures and Interpretive Guidelines for
164		Laboratories and Laboratory Services), issued by the Department of Health and
165		Human Services depending upon the tests they conduct, the source of the
166		specimens, and organizational structure. Each of these levels, except exempt
167		laboratories, has regulatory requirements concerning the qualifications of the
168		laboratory director, qualifications of laboratory personnel, proficiency testing ar
169		quality control as set forth in this Part. (See Appendix C).
170 171		1) Evennt Leberatory
1/1 172		1) Exempt Laboratory

173 174 175 176 177 178 179 180 181 182		A)	In order to qualify as an exempt laboratory, the laboratory must meet the definition of a "Class I Permit" laboratory and only conduct those tests specified in the regulations. As set forth in the Illinois Clinical Laboratory Act (Ill. Rev. Stat. 1989 and 1990 Supp., ch. 111½, par. 621 et seq.) ("the Act") and this Part, an exempt laboratory can be any "single practice of medicine, podiatry or dentistry" which owns and operates a laboratory exclusively for its patients, or a local health authority or designated agency which owns and operates a laboratory for its own clients or patients, at stated locations when testing is limited to tests which are set forth in Section 450.35(a).
184 185 186 187 188 189 190 191 192 193 194		B)	If an exempt laboratory conducts tests other than those listed it must seek another level of classification. Furthermore, health screening activities under Section 1-103 and 2-120 of the Act may be conducted by laboratories at locations other than the location or locations set forth in the permit or licensure application, however such health screenings must be conducted in accordance with Sections 450.1300, 450.1310, 450.1320, and 450.1330. An Exempt Laboratory is not exempt from the provisions of this Part concerning health screening.
195 196 197 198		C)	The Department expects physicians, podiatrists, dentists, local health authorities, and designated agencies to qualify as exempt laboratories.
199 200	2)	Class I	Laboratory
200 201 202 203 204 205 206 207 208 209 210		A)	As set forth in this Part, a "Class I Permit" laboratory can be any "single practice of medicine, podiatry or dentistry" which owns and operates a laboratory exclusively for its patients or a local health authority or designated agency which owns and operates a laboratory for its own clients or patients at stated locations when testing is limited to simple tests and those tests or categories of tests set forth by regulations as defined of this Part. Some or all testing may be done by a laboratory assistant under the direction of the physician, podiatrist or dentist.
211 212 213 214		B)	The "Class I Permit" laboratory must obtain a permit annually from the Department. Generally, the other major requirements are as follows:
215			i) the minimum level for the qualifications of the laboratory

216				director include any physician (M.D., D.O., or D.C.),
217				dentist, podiatrist, or person with at least a master's degree
218				with a major in chemical or biological sciences.
219				
220			ii)	the minimum level for the qualifications of laboratory
221				personnel include a laboratory assistant. Section 450.450 of
222				this Part specifies that a laboratory assistant is any person
223				who meets the education and experience requirements set
224				by the laboratory director.
225				The state of the s
226			iii)	the minimum level of proficiency testing requires
227			/	proficiency testing for all tests conducted by the laboratory
228				when available from an approved proficiency testing
229				service.
230				Sol vice.
231			iv)	the minimum level of quality control requires such testing
232			11)	for all tests conducted by the laboratory.
233				for all tests conducted by the laboratory.
234		C)	The D	repartment expects physicians, podiatrists, dentists, local
235		C)	hoolth	authorities, and designated agencies to seek "Class I Permit"
236				atory status. Health screening activities under Section 1-103
237				120 of the Act may be conducted by class I laboratories at
237				ons other than the location or locations set forth in the permit
238 239				-
240				ensure application, however such health screenings must be cted in accordance with Sections 450.1300, 450.1310,
240 241				
			430.1.	320, and 450.1330 of this Part.
242	2)	Class I	II I alaa	uo kours
243	3)	Class I	I Labo	ratory
244		A >	A .	Calian was TD will a
245		A)		forth in this Part, a "Class II Permit" laboratory can be any
246				tory at a stated location operated and maintained exclusively
247				e patients of physicians, podiatrists or dentists at that location
248				ho own the laboratory or are employed by the owner, or a
249				nealth authority or designated agency which owns and
250			-	es a laboratory for its own clients or patients or for clients or
251				ts of other local health authorities or designated agencies at
252			stated	locations.
253				
254		B)		Class II Permit" laboratory must obtain a permit annually
255				he Department. Generally, the other major requirements are
256			as foll	ows:
257				
258			i)	the minimum level for the qualifications of the laboratory

259 260 261 262				director includes a physician licensed to practice medicine in all of its branches, or a person with at least a master's degree with a major in chemical or biological sciences.
263 264			ii)	the minimum level for the qualifications of laboratory personnel includes a laboratory technician. Section 450.440
265				of this Part specifies that a laboratory technician is any
266				person who completes at least 60 hours of academic credit
267				including chemistry and biology, a high school graduate
268				who has completed a 1 year accredited training program, or
269				a high school graduate who has completed an official
270 271				military medical laboratory procedures course of at least 50
271 272				weeks.
273			;;;)	the minimum level of proficiency testing requires
274			iii)	the minimum level of proficiency testing requires proficiency testing for all tests conducted by the laboratory.
275				proficiency testing for air tests conducted by the laboratory.
276			iv)	the minimum level of quality control requires such testing
277			11)	for all tests conducted by the laboratory.
278				for all tests conducted by the facoratory.
279		$\stackrel{\mathbf{C}}{\longrightarrow}$	The D	epartment expects physicians, local health authorities, and
280		-,		ated agencies to seek "Class II Permit" laboratory status.
281				screening activities under Section 1-103 and 2-120 may be
282				cted by class II laboratories at locations other than the
283				on or locations set forth in the permit or licensure application,
284				ver such health screenings must be conducted in accordance
285				ections 450.1300, 450.1310, 450.1320, and 450.1330.
286				
287	4)	Class 1	III Lab e	oratory
288				
289		A)	As set	forth in this Part, a "Class III Permit" laboratory can be any
290				tory which is operated and maintained exclusively for the
291			purpos	ses of conducting health screening tests by a person,
292			corpor	ation, organization, association or group directly or
293			indirec	etly on a for profit basis. The health screening tests are listed
294			as gluc	cose and cholesterol by fingerstick in this Part.
295				
296		B)		Class III Permit" laboratory must obtain a permit annually
297			from t	he Department and must comply with Sections 450.1300,
298				810, 450.1320, and 450.1330. The "Class III Permit"
299				tory has no other regulatory requirements. Generally, the
300			other r	najor requirements are as follows:
301				

302				i)	the minimum level for the qualifications of the laboratory
303					director include a physician licensed to practice medicine in
304					all of its branches, or a person with at least a master's
305					degree with a major in chemical or biological sciences.
306					
307				ii)	the minimum level for the qualifications of laboratory
308				,	personnel include a laboratory assistant or laboratory
309					technician. Section 450.450 of this Part specifies that a
310					laboratory assistant is any person who meets the education
311					and experience requirements set by the laboratory director.
312					Section 450.440 of this Part specifies that a laboratory
313					technician is any person who completes at least 60 hours of
314					academic credit including chemistry and biology, a high
315					school graduate who has completed a 1 year accredited
316					training program, or a high school graduate who has
317					completed an official military medical laboratory
318					procedures course of at least 50 weeks.
319					procedures course of at reast 20 weeks.
320				iii)	the minimum level of proficiency testing requires
321				111)	proficiency testing for all tests conducted by the laboratory.
322					proficiency testing for an tests conducted by the laboratory.
323				iv)	the minimum level of quality control requires such testing
324				11)	for all tests conducted by the laboratory.
325					for all tests conducted by the laboratory.
326			C)	The F	Department expects corporations and groups to seek "Class III
327			<i>U</i>)		it" laboratory status.
328				T CITILI	it laboratory status.
329	<u>c</u> 5)	Licen	sed (Ce	ertified)	Laboratory
330	<u>_</u>		<u></u>	10111000/	,
331		<u>1</u> A)	As se	t forth i	n this Part, a " <u>licensed</u> Licensed" laboratory is acan be any
332		<u> </u>			rtified by the Department under the standards set forth in
333				•	nd regulations (CLIA Law) to accept and test clinical
334					ated location regardless of ownership which accepts
335					om a person, authorized by law in accordance with Article
336					tto submit such specimens when testing is limited to that
337					tin the qualifications of the Director as set forth in this Part.
338			WIIICI	1 15 WIUI	in the quantications of the Director as set forth in this fart.
339		2 B)	The li	icensed <u>'</u>	'Licensed" laboratory shall maintain certification status in
340		<u>~13</u>)			g as required by CLIA Law.must obtain a license annually
340 341					artment. Generally the other major requirements are as
342			follov	-	arthene. Soliciany the other major requirements are as
342 343			101101	v 5.	
344 344				i)	the minimum level for the qualifications of the laboratory
੭ਜ ਜ				7	the minimum tever for the qualifications of the factority

345			director includes a physician licensed to practice medicine
346			in all its branches who is Board certified or eligible or who
347			possesses acceptable qualifications as set forth in this Part,
348			or a person with at least a master's degree with a major in
349			chemical or biological sciences.
350			
351		ii)	the minimum level for the qualifications of laboratory
352			personnel include a general supervisor. Section 450.410 of
353			this Part specifies that a general supervisor may be any
354			physician with additional qualifications, a medical
355			technologist, a person with a master's degree in medical
356			laboratory science or other similarly qualified individuals.
357			
358		iii)	the minimum level of proficiency testing requires
359			proficiency testing for all tests conducted by the laboratory.
360			
361		iv)	the minimum level of quality control requires such testing
362			for all tests conducted by the laboratory.
363			
364	<u>d</u> €)	Physicians The Depa	rtment expects physicians, corporations, individuals, local
365			nd others that intend to conduct clinical tests on human
366		specimens for health	assessments or to diagnose, prevent or treat disease shall
367		obtain certification s	status by the Department in accordance with CLIA Lawto
368		seek "Licensed" Lab	poratory status. Health screening activities under Section—1-
369		103 and 2-120 of the	e Act may be conducted by a <u>certified</u> licensed laboratory at its
370		certificate address lo	ocations; other than the location or locations set forth in the
371		permit or licensure a	pplication, however, such health screeningscreenings events
372		_	ted in accordance with Sections 450.1300, 450.1310,
373		450.1320, and 450.1	330.
374			
375	(Source	ce: Amended at 44 Ill	. Reg, effective)
376	`		
377	Section 450.1	0 Definitions	
378			
379		"Accredited Instituti	on" or "Accredited College or University" means a college or
380			the United States which has been accredited by one of the

"Accredited Institution" or "Accredited College or University" means a college or university located in the United States which has been accredited by one of the regional accreditation programs recognized by the U.S. Office of Education or a college or university located outside the United States where the individual provides documentation that his/her education is equivalent to that provided in the United States by: documenting that the foreign degree has been accepted by an accredited institution in the United States at which the person is or was enrolled in a graduate program; or having his/her credentials evaluated by the Credentials Evaluation Service, Inc., Los Angeles, California.

389
390
391
392
393
394
395
396
397
398
399
400
401
402
403
404
405
406
407
408
409
410
411
412
413
414
415
416
417
418
419
420
421
422
423
424
425
426
427
428
429
430

388

"Act" or "Clinical Laboratory Act" — means-the Illinois Clinical Laboratory and Blood Bank ActIllinois Clinical Laboratory Act (Ill. Rev. Stat. 1987, ch. 111½, par. 621 et seq., as amended by P.A. 85-1025, effective June 30, 1988; P.A. 85-1202, effective August 25, 1988, and P.A. 85-1251 effective August 30, 1988.).

"Approved Clinical Laboratory" — a laboratory certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 means a clinical laboratory—(with a director at the doctoral level)—of a hospital, health department, university, or medical research institution; or a clinical laboratory having a license or class II permit under the Illinois Clinical Laboratory Act; or a blood bank licensed under the Blood—Bank Act; or a clinical laboratory licensed under the Clinical Laboratories Improvement Act of 1967; or, a clinical laboratory approved under 42 CFR 405, Subpart M effective September 30, 1977.

"Blood Bank Act" means the Illinois Blood Bank Act, (Ill. Rev. Stat. 1987, ch. 111½, pars. 601-101 et seq.)

"Class I Permit" means a permit issued to a single practice of medicine, podiatry or dentistry to own and operate a clinical laboratory at stated locations exclusively for the patients or the members of that practice, and is limited to simple tests and those tests or categories of tests set forth by the regulations promulgated pursuant to this Act; or a permit issued to a local health authority or designated agency to own and operate a clinical laboratory at stated locations without acceptance of referred testing, and is limited to those tests or categories of tests set forth by regulations promulgated pursuant to this Act. (Section 2-108 of the Act)

"Class II Permit" means a permit issued to the owner of a clinical laboratory at a stated location in which the laboratory is operated and maintained exclusively for the patients of the physicians, podiatrists or dentists who practice at that location and who own the laboratory or are employed by the owner; or

A permit issued to a local health authority or designated agency to own and operate a clinical laboratory at stated locations and at which referred testing may be accepted from other local health authorities or designated agencies; or

A clinical laboratory which fits the definition of a Class I Permit Laboratory but performs more complex tests than those under a Class I Permit.

Tests performed by a laboratory holding a Class II Permit shall be limited to

431	those tests or categories of tests set forth in the regulations promulgated pursuant
432	to this Act. (Section 2-109 of the Act)
433	
434	"Class III Permit" means a permit issued to the owner of a clinical laboratory
435	which is operated and maintained exclusively for the purpose of conducting
436	health screening tests by a person, corporation, organization, association or
437	group which provides health screening services in accordance with provisions of
438	Section 2-120 either directly or indirectly on a for profit basis. (Section 2-100 of
439	the Act)
440	
441	"CLIA Law" – the Clinical Laboratory Improvement Amendments of 1988
442	(amendments to the Public Health Service Act (42 USC 263a)) and the related
443	federal regulations. Establishes quality standards for laboratory testing performed
444	on specimens from humans, such as blood, body fluid, and tissue, for the purpose
445	of diagnosis, prevention, or treatment of disease, or of assessment of health.
446	or diagnosis, prevention, or treatment of disease, or or assessment of health.
447	"Clinical Laboratory" or "Laboratory" <u></u> means a facility which performs
448	laboratory tests or issues reports resulting from such tests. For the purposes of
449	this Part, "Clinical Laboratory" or "Laboratory" does not include forensic
450	laboratories. (Section 2-103 of the Act)
4 50 451	<u>Idoordiories.</u> (Section 2-103 of the Act)
452	"Complex Test" means any test which does not meet the definition of a simple test.
453	(Section 2-119 of the Act).
1 55 454	(Section 2-119 of the Act).
455	"Controlled Substance" - magne a drug substance or immediate procureer as
1 55 456	"Controlled Substance" — means a drug, substance, or immediate precursor as
	defined in the <u>Illinois Controlled Substances Act. Illinois Controlled Substance</u>
457 459	Act (III. Rev. Stat. 1987, ch. 56½, pars. 1100 et seq., as now and hereafter
458 450	amended.)
459 460	"Dontal Brootice Act" magne The Illinois Dontal Brootice Act (III Day Stat 1007
460 461	"Dental Practice Act" means The Illinois Dental Practice Act (Ill. Rev. Stat. 1987,
461 462	ch. 111, par. 2301 et seq., as now and hereafter amended.)
462	
463	"Demonstration of <u>Proficiency proficiency</u> " — <u>means the when a laboratory meets</u>
464	the standards for acceptable proficiency testing as stated in Section 450.720(a)(f)
465	by means of on site analysis of specimens sent to the laboratory by agencies
466	approved by the Department for that purpose.
467	
468	"Department" — means the Department of Public Health of the State of Illinois.
469	(Section 2-105 of the Act) the Illinois Department of Public Health.
470	
471	"Designated Agency" means an association, organization, group or agency which
472	operates a clinical laboratory for the purpose of meeting the requirements of a
473	state or federal program. (Section 2-122 of the Act).

474	
475	"Director" – the Director of the Department of Public Health.
476	
477	"Director of Clinical Laboratory" or "Laboratory Director" – an individual who
478	administers the technical and scientific operation of a clinical laboratory,
479	including the reporting of the findings of clinical laboratory tests. (Section 2-104
480	of the Act)
481	
482	"FDA" – Food and Drug Administration within the United States Department of
483	Health and Human Services (HHS).
484	
485	"Full-time Experienceexperience" — means experience in the field being referred
486	to consisting of at least 35 hours per week conducting activities required by the
487	specific position or field such as conducting the tests referred to in Section 2-103
488	of the Act.
489	
490	"Health Screening" – tests or categories of tests set forth in the Act and this Part
491	that are performed for the purpose of assessing a phase of the general state of
492	health of human subjects (Section 2-120 of the Act).
493	
494	"HHS" – the United States Department of Health and Human Services.
495	
496	"Hospital Licensing Act" means the Hospital Licensing Act (Ill. Rev. Stat. 1987,
497	ch. 111½, pars. 142 et seq., as now and hereafter amended.)
498	
499	"License" means a license issued to the owner, local health authority or
500	designated agency or person to operate a clinical laboratory at a stated location
501	to accept specimens from any person authorized to submit such specimens under
502	this Act, with test limitations based upon the qualifications of the Director as set
503	forth by the regulations promulgated pursuant to this Act. (Section 2-111 of the
504	Act).
505	
506	"Licensed Clinical Laboratory" – laboratory licensed (certified) by the Centers for
507	Medicare & Medicaid Services (CMMS) in accordance with CLIA.
508	
509	"Local Health Authority" means the full-time, official health department or Board
510	of Health, as recognized by the Department, which has jurisdiction over a
511	particular geographical area. (Section 2-121 of the Act).
512	r
513	"Medical Practice Act" means the "Medical Practice Act of 1987" (III. Rev. Stat.
514	1987, ch. 111, pars. 4401-1 et seq., as now and hereafter amended.)
515	170., em 111, paisi 1101 1 et seqi, as non and neroarter amendeal)
516	"Minor Test" means any uncomplicated laboratory examinations and procedures
-10	initial rest incums any ancomplicated adoptatory examinations and procedures

517	which the Director of the Department determines have an insignificant risk of
517	erroneous result including those which have been approved by the United States
519	Food and Drug Administration for home use, which employ methodologies that
520	are so simple and accurate as to render the likelihood of erroneous results
	*
521 522	negligible. Tests determined by the Director to be "minor" and permissible for a
	Registration class laboratory are set forth in Section 450.35(a).
523	
524	"Physician" — means, unless otherwise indicated in the this Act and this Part, a
525	person licensed by the Department of Professional Regulation, pursuant to the
526	requirements of the Medical Practice Act of 1987; (i.e., a physician licensed to
527	practice medicine in all its branches and a chiropractic physician) or a person
528	licensed as a physician under the laws of another state or territory of the United
529	States. (Section 2-116 of the Act).
530	
531	"Podiatry Act" means Podiatric Medical Practice Act of 1987 (Ill. Rev. Stat. 1987)
532	ch. 111, pars. 4801 et seq., as now and hereafter amended.)
533	
534	"Prepackaged Reagent Analyzer Analyser" — means an automated instrument in
535	which a specimen or a diluted specimen is reacted with reagents contained within
536	individual packet(s) containing all of the measured reagents required for the
537	analysis for a given analyte.
538	,,
539	"Proficiency Testing" means a program for monitoring laboratory performance
540	on a periodic basis which is adopted or approved by the Department. (Section 1-
541	123 of the Act.)
542	123 of the rect)
543	"Simple Test" means a test or categories of tests which generally have the
544	following characteristics:
545	John Wing Characteristics.
546	Interpretation of a visual signal by pattern recognition, color definition or
547	numeric information using an established control example which can be
548	observed directly by the operator and requires no manipulation or
549	
550	interpolation by the operator to derive a result; or
551	The use of simple addition, subtraction, multiplication or division; or
552	
553	The use of manufacturer prepared reagents or solutions which are
554	combined without requiring numerous (i.e. no more than five sequential
555	steps which should not include sample acquisition or sample preparation
556	such as centrifuge to obtain serum) specific calibrated volume
557	measurements or sequential applications.
558	
559	In addition, the following considerations are used to determine if a test or test

In addition, the following considerations are used to determine if a test or test

560 procedure meets the definition of Simple Test: the examinations and procedures 561 performed and the methodologies employed, the degree of independent judgment involved, the amount of interpretation involved, the difficulty of the calculations 562 563 involved, the calibration and quality control requirements of the instruments used, 564 the type of training required to operate the instruments used in the methodology, 565 and such other factors as the Director considers relevant. 566 567 Interpretation of the types of tests or categories of test which meet this definition shall be determined by the Department in consultation with the Clinical 568 569 Laboratory and Blood Bank Advisory Board established by Section 5-101 of the 570 Act. (Section 2-118 of the Act). 571 572 The Department will compile a list of tests and test procedures which it 573 determines meets the definition of a simple test. Such compilation will be 574 available upon request and updated annually. 575 "Single Practice ractice" — means a medical, dental or podiatric practice, or a 576 577 partnership, professional service corporation, or medical corporation of one or more licensed practitioners who share facilities, personnel, income and expenses 578 579 for a clinical laboratory that is used solely as an adjunct to the care of patients of 580 the members of the single practice. 581 582 "Test" – means laboratory examinations and issuance of reports resulting from 583 the biological, microbiological, serological, chemical, immunohematological, 584 radioimmunological, hematological, biophysical, cytological, pathological, 585 toxicological or other examination of materials derived from the human body for 586 the purposes of providing information for the diagnosis, prevention or treatment 587 of any disease or impairment of, or the assessment of, the health of humans including determining drug use by humans. (Section 2-117 of the Act). 588 589 590 "Toxicology Laboratory" – means-a licensed laboratory that which performs tests 591 to detect drug abuse in the workplace, among job applicants, or for other similar 592 purposes. 593 "Waived Test" – a test system, assay or examination that HHS has determined 594 595 meets the CLIA statutory criteria as specified for waiver under Section 353(d)(3) 596 of the Public Health Service Act that has been determined to be so simple as to 597 pose no risk of harm if performed incorrectly. 598 599 (Source: Amended at 44 Ill. Reg. _____, effective _____) 600 601 Section 450.20 Permit and License (Certification) Application

602

503	a)	A laboratory that is required to obtain a license or permit pursuant to this Act by
504		July 1, 1989, but was previously exempt from such requirement, shall submit an
505		application to the Department, but will have until December 31, 1989, to comply
506		with this requirement. Any such laboratory which complies with this deadline
507		will be permitted to continue operation until receipt of a permit or license or
508		notice of denial of application for a permit or license from the Department.
509		(Section 3-103(b) of the Act)
510		
511	<u>a</u> b)	All applications shall be submitted on forms provided by the Department, shall be
512		notarized, and shall include all information requested on the form.
513		· · · · · · · · · · · · · · · · · · ·
514	<u>be</u>)	If during the calendar year in which the licensed (certified) providerlicense,
515	_ ,	permit, or renewal thereto has been issued there is a change of owner, location, or
516		name of the laboratory, the Department shall be notified of the change in writing
517		within 30 days following the change by one of the following methods: prior to
518		such change.
519		
520		1) U.S. Mail to: Illinois Department of Public Health, Office of Health Care
521		Regulation, Division of Health Care Facilities and Programs, 525 West
522		Jefferson Street, Fourth Floor, Springfield, Illinois 62761; or
523		
524		2) Facsimile to: 217-782-0382, attention: Division of Health Care Facilities
525		and Programs.
526		
527	d)	If the license or permit is to be issued to two or more persons who are co/owners,
528	/	all such persons shall be identified upon the application for license or permit or
529		renewal of license or permit and all such persons shall sign such application and it
530		shall be notarized.
531		
532	e)	An application for a license or permit, where the owner is a corporation, shall
533	-/	clearly disclose the names of all persons owning 5% or more of the shares of the
534		corporation. A duly authorized officer of the corporation shall sign the application
535		and it shall be notarized.
536		
537	<u>c</u> f)	The description of the program shall be provided in sufficient detail to permit the
538	==/	Department to determine the fields of science represented by the services of the
539		laboratory and the tests which may fall within the scope of its program and
540		services.
541		
542	(Sour	ce: Amended at 44 Ill. Reg, effective)
543	(2361	,,
544	Section 450 3	80 Laboratories Covered

645

546	The following	g are required to be licensed (certified) pursuant to CLIA Law:			
547 548 549 550 551	<u>a)</u>	All clinical laboratories and blood banks located within the State of Illinois. This includes facilities that issue reports resulting from laboratory examinations, but do not perform laboratory examinations at that facility. (See Section 2-103 of the Act.)			
552 553 554 555 556	<u>b)</u>	Laboratories located in hospitals licensed under the Hospital Licensing Act that are not operated by the governing authority of the hospital, including laboratories operating under a lease arrangement with another person or entity.			
550 557 558 559 560	<u>c)</u>	Laboratories outside of Illinois receiving specimens referred from laboratories located in Illinois shall be certified under CLIA Law, or certified by, and in good standing with, their state laboratory program.			
561 562 563 564 565 566	a)	This Section provides references to help understand the differences among these laboratories. The Department assigns an identification number to a laboratory at the time of license or permit application. This number is only for purposes of filing material for that laboratory in the Department. Such identification number is not a license or permit. A license or permit is issued only after an inspection of the facility finds compliance with all pertinent requirements, except for a class I permit laboratory where an inspection is not required.			
568 569 570 571		1) An exempt laboratory meets the criteria set forth in Section 1-103(c) of the Act, and Sections 450.30(c)(3) and 450.35(a) of this Part.			
572 573 574 575		2) A class I permit laboratory meets the criteria set forth in Section 2–108 of the Act; Section 6–101(2)(a) of the Act; and Sections 450.30(b) and 450.35(b) of this Part.			
575 576 577 578		A class II permit laboratory meets the criteria set forth in Section 2-109 of the Act; Section 6-101(2)(b) of the Act; and Sections 450.30(b) and 450.35(c) of this Part.			
580 581 582 583		4) A class III permit laboratory meets the criteria set forth in Section 2-110 of the Act; Section 6-101(2)(c) of the Act; and Sections 450.30(b) and 450.35(d) of this Part.			
584 585 586		A licensed laboratory meets the criteria set forth in Section 2-111 of the Act; Section 6-101(2)(d) of the Act; and Sections 450.30(b) of this Part with no testing limitations, provided the director qualifies.			
587 588	b)	The following are required to obtain a permit or be licensed pursuant to the Act:			

- 1) All clinical laboratories and Blood Banks located within the State of Illinois except as otherwise provided in Section 450.30(c). This includes facilities that issue reports resulting from laboratory examinations, but do not perform laboratory examinations at that facility. (See Section 2-103 of the Act).
- 2) Laboratories located in hospitals licensed under the Hospital Licensing
 Act but where the laboratory is not operated by the governing authority of
 such hospital, including laboratories operating under a lease arrangement
 with another person or entity.
- 3) Laboratories outside of Illinois receiving specimens referred from laboratories located in Illinois that are required to obtain a license or permit under this Act.
- c) The following are not required to obtain a permit or be licensed under the Clinical Laboratory Act:
 - 1) Clinical laboratories operated by the United States Government.
 - Clinical laboratories located in hospitals licensed under the Hospital
 Licensing Act that are under the control of the governing board of such
 hospitals owned by the exact same entity identified as owner/operator of
 the hospital as indicated on the last hospital license application filed with
 the Department; located at the same site and contiguous with the hospital;
 subject to the regulations and hospital by laws; and where the entity which
 receives payment for the laboratory services is the same entity that owns
 the hospital.
 - Exempt Laboratories: Laboratories which fit the definition of Class I
 Permit Laboratories but perform a small number of minor tests as
 compared to other Class I Permit Laboratories as set forth by regulations
 promulgated pursuant to this Act (See Section 450.35(a)), or any tests
 performed by the physician, podiatrist or dentist for the benefit of his or
 her patients, do not require a license or permit. (See Section 1-103(c) of
 the Act).
 - 4) Laboratories which only perform health screenings in accordance with Section 2-120 of The Act and Sections 450.1300, 450.1310, 450.1320, and 450.1330 of this Part, on a not-for-profit or free-of-charge basis are exempt from all other provisions of this Act. (Section 1-103(d) of the Act)

		5)	perfo	enforcement agencies and probation and court services departments orming urinalysis and blood tests to determine drug and alcohol use umans. (Section 1–103(e) of the Act)
(S	Sourc	e: An	nended	at 44 Ill. Reg, effective)
Section 4 (Repeale		5 Tes	ting Li	mitations for Exempt, Permit and Licensed Laboratories
				ests as defined in Section 2-117 of the Act which can be performed by ulated by the Act.
a))		npt Labo wing tes	oratories as defined in Section 1–103(c) of the Act may perform the sts:
		1)	Spec	ific tests and test procedures permissible are the following:
			A)	Urinalysis measured by the use of a chemically impregnated strip (dipstick) or tablet;
			B)	Hematocrit by centrifugation;
			C)	Occult blood;
			D)	Urine pregnancy testing (semi-quantitative chorionic gonadotropin);
			E)	Hemoglobin;
			F)	Red Blood Cell (RBC) sickle cell screen using dithionite, sodium hydrosulfite;
			G)	Wet mounts for Yeast or Trichomonas;
			H)	Blood cholesterol;
			I)	Blood glucose;
			J)	Erythrocyte protoporphyrin using a hematofluorometer;
			K)	Screening for drugs of abuse by latex agglutination or any other method which meets the simple test definition;

775		L)	Gonorrhea limited to cultures for growth or no growth, oxidase and
776			lactidase, Gram stain;
777			
778		M)	Microscopic examination of pinworm preparation; and
779		ŕ	
780		N)	Strep Screening Tests: Rapid group A strep antigen tests. (Section
781		ŕ	1–103(c) of the Act)
782			
783		$\frac{2}{2}$ Any t	est performed (i.e., conducted and interpreted) by a physician,
784			strist or dentist for the benefit of his or her patients. (Section 1-103(c)
785			? Act);
786		· · · · · · · · · · · · · · · · · · ·	
787		3) Any t	tests and test procedures approved by the United States Food and
788		Drug	Administration for over the counter sale.
789		Diag	Training training for over the counter state.
790		4) RPR	tests for syphilis may be performed by exempt laboratories operated
791			cal health departments under the following conditions:
792		<i>Oy</i> 100	car nearth departments under the following conditions.
793		A)	The Department has determined that the area served by the
794		11)	laboratory has a high incidence of early syphilis;
795			laboratory has a high incidence of earry syphinis,
796		B)	The laboratory has a written procedure for the performance of RPR
797		D)	syphilis testing which complies with Section 450.1140 and Section
798			450.1150(f)(l) of this Part and maintains documentation of
799			compliance with this procedure;
800			compliance with this procedure;
300 301		C)	The laboratory has written procedures for training of personnel
301 302		 	who perform the tests;
302 303			who perform the tests,
303 304		D)	The laboratory suggestfully partiainates in an approved proficionary
30 4 305		D)	The laboratory successfully participates in an approved proficiency
805 806			testing program for syphilis serology;
		E	All angeimans tosted are submitted to a laboratory approted by the
307		E)	All specimens tested are submitted to a laboratory operated by the
808 809			Department for confirmation of the test results; and
		E)	The lebenders is subject to increasing be the Department and
310		F)	The laboratory is subject to inspection by the Department and
311			agrees to immediately cease RPR syphilis testing if the Department
312			determines that the laboratory is not in compliance with these
313			conditions.
314	1.3		'.T. 1
315	b)		it Laboratories as defined in Section 2-108 of the Act may perform
316		the following	y tests:

318		1) All tests that can be performed by Exempt Laboratories;	
819			
320		2) Any simple tests as defined in Section 450.10 (Section 2-108 of the A	ct);
321		and	
322			
323		3) Those tests or categories of tests set forth by the regulations promulge	ated
324		pursuant to the Act. The Department may give approval to a Class I	
325		permit laboratory to perform up to three tests which do not fall within	the
326		definition of a simple test, when the laboratory director submits	
327		documentation describing the purpose of each test, how it is performe	d,
328		the specific training and experience of the personnel performing the to	
329		and necessary quality control procedures appropriate to the test(s), and	
330		extent of supervision provided by the laboratory director. The Departr	
331		shall grant approval based upon the following criteria:	110111
332		shan grant approval based apon the following effectu.	
332 333		A) the test(s) is unique to a specific healthcare practice and not re	مطناء
333 334		available from a licensed clinical laboratory (e.g., not perform	
33 4 335		by a licensed clinical laboratory or hospital laboratory within :	
333 336		miles); or	70
330 337		innes), or	
838		D) on site magnet accults (a a magnitude and magnitude in loss time the	0.40
339		B) on-site prompt results (e.g., results are required in less time the	## + b
		sending a specimen to a reference laboratory) are necessary for	
340		treatment or care of the patients of the healthcare provider bec	ause
341		of the nature of the practice.	
342			
343	e)	Class II permit Laboratories as defined in Section 2-109 of the Act may perfe	rm
344		the following tests:	
345			
346		1) All tests that can be performed by Exempt Laboratories;	
347			
348		2) All tests that can be performed by the Class I laboratory as detailed in	:
349		subsection (b).	
350			
351		3) Any complex tests.	
352			
353	d)	Class III Permit Laboratories as defined in Section 2-110 of the Act may perf	orm
354		the following tests:	
355			
356		Any health screening tests as defined in Section 450.1300(a).	
357	e)	Licensed Clinical Laboratories as defined in Section 2-111 of the Act may	
358	- /	perform the following tests:	
359			
360		1) All tests that can be performed by Exempt Laboratories;	
		,	

861		2)	All toots that can be marformed by the Class I laboratory as detailed in
362		2)	All tests that can be performed by the Class I laboratory as detailed in
363 364			subsection (b).
365		2)	Any complex tests
366 366		3)	Any complex tests.
367	(Sour	ce: Ren	ealed at 44 Ill. Reg, effective)
368	(Bourt	cc. rep	calca at 11 m. reg
369	Section 450.5	50 Inco	rporated and Referenced Materials
370	TD1 C 11 :		
371	The following	g materi	als are incorporated or referenced in this Part:
372	,	TEN C	
373	a)	The fo	ollowing State of Illinois Statutes are referenced in this Part:
374		1)	
375		1)	Illinois Clinical Laboratory and Blood Bank Act [210 ILCS 25] Illinois
376			Clinical Laboratory Act (Ill. Rev. Stat. 1987, par. 621 et seq. as amended
377			by P.A. 85-1025, effective June 30, 1988; 85-1202, effective August 25,
378			1988; P.A. 85-1251, effective August 30, 1988.) (Section 450.10)
379			
380		2)	Illinois Blood Bank Act (Ill. Rev. Stat. 1987, ch. 111½, pars. 601-101 et
381			seq.) (Section 450.10 and 450.1200(a)(1))
382			
383		<u>2</u> 3)	Illinois Dental Practice Act [225 ILCS 25](Ill. Rev. Stat. 1987, ch. 111,
384			par. 2301 et seq.) (Section 450.10)
385			
386		<u>3</u> 4)	Hospital Licensing Act [210 ILCS 85] (Ill. Rev. Stat. 1987, ch. 1111/2, pars
387			142 et seq.) (Section 450.10, 450.30, 450.1200(a)(1), 450.1300(b)(3))
388			
389		<u>4</u> 5)	Medical Practice Act of 1987 [225 ILCS 60] (Ill. Rev. Stat. 1987, ch. 111,
390			pars. 4401 et seq.) (Section 450.10)
391			
392		<u>5</u> 6)	Podiatric Medical Practice Act of 1987 [225 ILCS 100] (Ill. Rev. Stat.
393			1987, ch. 111, pars. 4801 et seq.) (Section 450.10)
394			
395		<u>6</u> 7)	Code of Civil Procedure, Article III (Administrative Review Law) [735]
396			ILCS 5/Art. III] Administrative Review Law (Ill. Rev. Stat. 1987, ch. 110,
397			pars. 3-101 et seq.) (Section 450.40(b)(5))
398			
399		<u>7</u> 8)	Illinois Controlled Substances Act [720 ILCS 570] (Ill. Rev. Stat. 1987, ch
900			56½, pars. 1100 et seq.) (Section 450.10)
901		-	
902	b)	The fo	ollowing State of Illinois Regulations are referenced in this Part:
202			

904 905		1)		<u>Discharge Criteria (</u> 35 Ill. Adm. Code 307) on 450.330(d)(5))
906 907 908 909		2)	Storag	ards for Owners and Operators of Hazardous Waste Treatment, ge, and Disposal Facilities (35 Ill. Adm. Code 724) on 450.330(e)(4)(A))
910 911 912		3)		Waste Disposal: General Provisions (35 III. Adm. Code 809) on 450.330(e)(4)(e)(i))
913 914 915	c)			g federal guidelines Federal Guidelines, statutes Statutes, federal deral Regulations, and other materials are incorporated by reference:
916 917 918		<u>1)</u>	<u>Federa</u>	al Regulations and Statutes:
919 920 921			<u>A</u> 1)	42 CFR 493, Laboratory Requirements (CLIA regulations) (October 1, 2018)42 CFR 405, Subpart M (1988) (Section 450.10)
922 923 924 925			<u>B</u> 2)	21 CFR 600-680, <u>Biologics (April 1, 2018(1988)</u> (Section 450.1150(g)(1))
926 927 928 929			<u>C)</u>	Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, Title II – Preventing Health Care Fraud and Abuse; Administrative Simplification; Medical Liability Reform, Section 264 – Recommendations with Respect to Privacy
930 931 932 933				of Certain Health Information (August 21, 1996), Assistant Secretary for Planning and Evaluation, Room 415F, U.S. Department of Health and Human Services, 200 Independence Avenue, SW, Washington DC 20201
934 935 936				Also available online at: https://aspe.hhs.gov/report/health-insurance-portability-and-accountability-act-1996
937 938			<u>D)</u>	42 USC 263a, Certification of Laboratories (January 12, 2018)
939 940 941 942		3)	Finance (See S	atory Qualification Appraisal Personnel Form Health Care eing Authority (HCFA) HCFA 3084 OMB No. 0938 0049 ection 400.210(a), 450.410(b), 450.420(a), 450.430(a), 450.440(a) 50.450(a))
943 944 945		<u>2)</u>	Federa	al Guidelines and Other Materials:
946			<u>A</u> 4)	<u>GP17-A3 Clinical Laboratory Safety; Approved Guideline – Third</u>

947			Edition, Clinical and Laboratory Standards Institute (CLSI) (June
948			2012)National Committee for Clinical Laboratory Standards
949			(NCCLS), 950 West Valley Road, Suite 2500, Wayne PA 10987
950			Also available online at: https://clsi.org/media/1381/
951			gp17a3_sample.pdf "Protection of Laboratory Workers from
952			Infectious Disease Transmitted by Blood, Body Fluid and Tissue"
953			Document #M29 T, Vol. 9, #1 (January 1989), 771 East Lancaster
954			Avenue, Villanova, PA 19085
955			
956		5) 42 CF	FR 405.1317 (b)(1) (1988)
957			
958		<u>B)</u>	Public Health Service Act, Subpart 2, Section 353 – Clinical
959			Laboratories, Certification of Laboratories (1997), Public Health
960			Law, CDC, 1600 Clifton Road, Atlanta GA 30329-4027 (Section
961			<u>450.10)</u>
962			Also available online at: https://wwwn.cdc.gov/cliac/pdf/
963			Addenda/cliac0910/Addendum%20C_Yost.pdf
964			
965		<u>C</u> 6)	Reference Volume for Human Cytogeneticists, Molecular
966			Geneticists, Technicians, and Students for the Interpretation and
967			Communication of Human Cytogenetic and Molecular
968			Cytogenomic Nomenclature: ISCN 2016 – An International
969			System for Human of Cytogenetic Nomenclature (2016), S. Karger
970			AG, Medical and Scientific Publishers, P.O. Box <u>CHCh-4009</u>
971			Basel, (Switzerland) 1985. (See Section 450.1150(j)(3)(C)(i))
972			
973	d)		tions by reference of federal regulations and the standards of
974		•	cognized organizations refer to the regulation and standards on the
975		-	l and do not include any additions or deletions subsequent to the date
976		specified.	
977	40		14.74.7
978	(Sour	ce: Amended a	tt 44 Ill. Reg, effective)
979		GLIDD A DEL	D. DUDEGTODG OF GLOVIGAL LABORATORIES
980		SUBPART	B: DIRECTORS OF CLINICAL LABORATORIES
981	C 41 450	210 0 1'6' 4	
982 983	Section 450.	210 Quanneat	ions of the Director of a Clinical Laboratory
984	A director ca	ndidate shall m	eet one or more options of the qualification requirements in 42 CFR
985	493, Subpart		ect one of more options of the quantication requirements in 12 of K
986			
987	a)	Qualification	s of Directors. Every clinical laboratory shall be under the
988	,		and direction of a Director who possesses one of the following
989		qualifications	s. These qualifications must be documented on the Department form

990 entitled "Laboratory Personnel Qualifications Appraisal". (See Section 991 450.50(c)(3)992 993 1) The individual is a physician licensed to practice medicine in all its 994 branches in Illinois and certified by the American Board of Pathology or 995 the American Osteopathic Board of Pathology in clinical pathology, or 996 who possesses qualifications which are equivalent to such certification 997 (Board eligible). 998 999 2) The individual is a physician licensed to practice medicine in all its 1000 branches in Illinois with special qualifications in the performance of the 1001 test or tests offered by the clinical laboratory, whose training and 1002 experience are acceptable to the Department. 1003 1004 AA physician having not less than one year of post-graduate training 1005 in diagnostic laboratory procedures in a residency training program 1006 approved for training purposes by the American Board of 1007 Pathology or the American Osteopathic Board of Pathology. 1008 1009 B) A physician having not less than two years of supervised 1010 experience in an approved clinical laboratory carrying out 1011 procedures in the field or fields or science which encompass the 1012 program and services provided by the laboratory which this 1013 individual will direct. 1014 1015 \mathbf{C} To be director of a genetics laboratory, the physician shall have 4 1016 or more years of post-graduate genetics laboratory experience in an 1017 approved clinical laboratory. 1018 1019 To be director of a histocompatibility laboratory, the physician D) 1020 shall have 4 or more years of immunology laboratory experience in 1021 an approved clinical laboratory, subsequent to becoming a 1022 physician, 2 years of which have been in histocompatiblity testing. 1023 1024 E) To be director of a toxicology laboratory which performs tests for 1025 controlled substances, the physician shall have 4 or more years of 1026 post-graduate experience in an approved clinical laboratory which 1027 performs tests for controlled substances or have formal academic 1028 education from an accredited institution in drug metabolism, drug 1029 kinetics, and the use and limitations of analytical procedures used 1030 in drug analysis. 1031 1032 3) In the case of a laboratory, the principal place of business of which is

1033		outsi	de the State of Illinoi.
1034		praci	tice medicine in all of
1035		quali	ifications in the perfo
1036		labo i	ratory with training a
1037			
1038		A)	A physician having
1039			in diagnostic labor
1040			approved for traini
1041			Pathology or the A
1042			
1043		B)	A physician having
1044			in an approved clir
1045			field or fields of so
1046			services provided l
1047			direct.
1048			
1049		$\stackrel{\mathbf{C}}{}$	To be director of a
1050			or more years of p
1051			approved clinical l
1052			
1053		D)	To be director of a
1054			shall have 4 or mo
1055			an approved clinic
1056			physician, 2 years
1057			
1058		E)	To be director of a
1059			controlled substan
1060			post-graduate expe
1061			performs tests for
1062			education from an
1063			kinetics, and the us
1064			in drug analysis.
1065			
1066	4)	The i	individual is a physici
1067		in all	its branches or a chi
1068		licen	sed in Illinois.
1069			
1070	5)	The i	individual holds a deg
1071	•		ersity acceptable to th
1072			egical sciences and he
1073			ciency in those tests f
1074		2 0	· ·

1075

outside the State of Illinois, the individual is a physician licensed to practice medicine in all of its branches in that state and possesses special qualifications in the performance of the test or tests offered by the clinical laboratory with training and experience acceptable to the Department.

- A) A physician having not less than one year of post-graduate training in diagnostic laboratory procedures in a residency training program approved for training purposes by the American Board of Pathology or the American Osteopathic Board of Pathology.
- B) A physician having not less than two years supervised experience in an approved clinical laboratory carrying out procedures in the field or fields of science which encompass the program and services provided by the laboratory which this individual will direct.
- C) To be director of a genetics laboratory, the physician shall have 4 or more years of post graduate genetics laboratory experience in an approved clinical laboratory.
- D) To be director of a histocompatibility laboratory, the physician shall have 4 or more years of immunology laboratory experience in an approved clinical laboratory, subsequent to becoming a physician, 2 years of which have been in histocompatibility testing.
- E) To be director of a toxicology laboratory which performs tests for controlled substances, the physician shall have 4 or more years of post graduate experience in an approved clinical laboratory which performs tests for controlled substances or have formal academic education from an accredited institution in drug metabolism, drug kinetics, and the use and limitations of analytical procedures used in drug analysis.
- 4) The individual is a physician (i.e. physician licensed to practice medicine in all its branches or a chiropractic physician), dentist or podiatrist licensed in Illinois.
- 5) The individual holds a degree above baccalaureate level from a college or university acceptable to the Department, with a major in chemical or biological sciences and has satisfied the Department of his training and proficiency in those tests for which this license is sought.
 - A) An individual who holds an earned graduate degree above the

baccalaureate level from an accredited institution in a medical laboratory science or with a chemical or biological science as a major subject may direct a laboratory which requires a class I, II, or III permit or a license, provided the individual documents that the individual has had 3 more years of full-time clinical laboratory training and experience in an approved clinical laboratory, subsequent to graduation, in each area of the laboratory in which testing is performed. The laboratory areas are bacteriology/mycology, parasitology, virology, immunology/serology, hematology, immunohematology, and chemistry. Experience as a technologist in an approved clinical laboratory which was gained prior to acquiring the graduate degree may be substituted on an equivalency basis of 1.5 years of such experience for every 1 year of post degree training and experience required; and experience as a general supervisor in an approved clinical laboratory, which was gained prior to acquiring such degree, may be substituted on a 1-for-1 basis. Such documentation shall be made on a form entitled "Laboratory Personnel Qualifications Appraisal" (See Section 450.50(c)(3)).

- B) To be director of a histocompatibility laboratory, the individual shall hold an earned doctoral degree from an accredited institution with a chemical or biological science as a major subject and have 4 or more years of postdoctoral laboratory experience in immunology in an approved clinical laboratory, 2 of which have been in histocompatibility testing.
- C) To be director of a genetics laboratory, the individual shall hold an earned doctoral degree from an accredited institution with a chemical or biological science as a major subject and have 4 or more years of postdoctoral genetics laboratory experience in an approved clinical laboratory.
- D) To be director of a toxicology laboratory which performs tests for controlled substances, the individual shall hold an earned doctoral degree from an accredited institution with a chemical or biological science as a major subject and have 4 or more years of post-graduate experience in an approved clinical laboratory which performs tests for controlled substances; or have formal academic education from an accredited institution in drug metabolism, drug kinetics, and the use and limitations of analytical procedures used in drug analysis.

119		6)	An individual listed as the Director, prior to August 23, 1965, of one
120			clinical laboratory which was registered with the Department under the
121			provisions of this Act, may continue to direct one laboratory, and an
122			individual who directed two such laboratories simultaneously may
123			continue to direct two laboratories, except that the Department, upon
124			recommendation of the Clinical Laboratory and Blood Bank Advisory
125			Board, may, as a condition precedent to the issuance of an original
126			license hereunder, require such individual to pass a practical examination
127			in the event that it deems such an examination necessary to determine the
128			competence of the individual to direct a clinical laboratory. The
129			Department will not require a practical examination.
130			
131		7)	The individual is a physician licensed to practice medicine in all its
132		,	branches in Illinois.
133			
134		8)	To be director of a pathologic anatomy laboratory, the individual must be
135		- /	a physician licensed to practice medicine in all its branches in Illinois and
136			certified or determined to be board eligible by the American Board of
137			Pathology in anatomic pathology or the American Osteopathic Board of
138			Pathology in anatomic pathology, or the individual is a dentist licensed in
139			Illinois and certified by the American Board of Oral Pathology; except
140			that bone marrow interpretations may be done by a hematologist who is
141			certified or determined to be Board eligible by the American Board of
142			Internal Medicine.
143			The Har Metherne.
144	b)	Mini	imum requirements for laboratory direction and staffing. A permit or license
145	0)		perate a clinical laboratory shall be issued only if the following technical staf
146			employed to provide supervision and direction during testing as required by
147			lations promulgated pursuant to this Act:
148		regui	unions promuigued pursuant to mis rici.
149		1)	A class I permit requires a Director qualified under subsections (1), (2),
150		1)	(4), (5), (6) or (8) of subsection (a) of this Section to provide supervision
151			and direction, with or without a laboratory assistant.
152			and direction, with or without a taboratory assistant.
153		2)	A class II permit requires a Director qualified under subsections (1), (2),
154		2)	(5), (6), (7) or (8) of subsection (a) of this Section to provide supervision
155			
156			and direction, with the employment of technicians or technologists.
150		2)	A class III normit requires a Director qualified under subsections (1) (2)
		3)	A class III permit requires a Director qualified under subsections (1), (2),
158			(5), (6) or (7) of subsection (a) of this Section to provide supervision and
159			Direction, with the employment of laboratory assistants or technicians.
160		45	A 1:
161		4)	A license requires a Director qualified under subsections (1), (2), (3), (5),

1162		(6) or (8) of subsection (a) of this Section to provide supervision and
1163		direction, with the employment of a general supervisor if necessary to
1164		provide supervision in the absence of the Director.
1165		r · · · · · · · · · · · · · · · · · · ·
1166	(Source	: Amended at 44 Ill. Reg, effective)
1167 1168	Section 450.22	0 Operational Participation of the Director
1169		
1170		The laboratory director is responsible for the operation and administration of the
1171		laboratory, including the employment of personnel who are qualified and
1172		competent to perform test procedures, maintain records, and report test results
1173	1	promptly, accurately and proficiently to assure compliance with applicable CLIA
1174]	<u>Law.</u>
1175		
1176		The laboratory director, if qualified, may perform the duties of the technical
1177		supervisor, technical or clinical consultant, general supervisor, and testing
1178		personnel, or delegate these responsibilities to personnel meeting the
1179	9	qualifications.
1180		
1181		The laboratory director shall be accessible to the laboratory to provide onsite,
1182	1	telephone or electronic consultation.
1183		
1184		The laboratory director shallmust follow the weekly schedule established in
1185	;	accordance with Section 450.1110(d), except for absences due to emergencies,
1186	İ	illness, or professional meetings. In case of an absence for vacation or other
1187]	purposes that which does not exceed 30 days, the owner shall ensure director
1188	•	coverage by designating an acting director who is qualified to direct that
1189]	laboratory.
1190		
1191	<u>e</u> b)	If the laboratory director is absent for In case of an absence which is more than 30
1192		days, the owner shall designate an acting <u>laboratory</u> director to direct the
1193]	laboratory in the Director's absence who meets the qualifications in 42 CFR 493,
1194		Subpart Mset forth in Section 6-101 of the Act which are appropriate for the
1195	j	permit or license held by the laboratory. If the absence of the laboratory director
1196		will be permanent, the owner shall immediately submit a request for a laboratory
1197	9	director change to the Department. The owner shall submit to the Department
1198	i	immediately after 30 days has elapsed, a personnel form for the acting director.
1199		This individual may be the same individual designated in accordance with Section
1200		450.220(a) or another individual. The acting director may continue to function as
1201		director for a period of 90 days after the personnel form is received.
1202		
1203	c) :	An acting director may not serve as director for a period of time exceeding 120
1204		days, 90 days after the personnel form was received by the Department, unless the

205	θ	wner informs the Department that the acting director is now the director.
206		
207	(Source:	Amended at 44 Ill. Reg, effective)
208	G .4 450.000	
209	Section 450.230	Number of Laboratories Permitted to Operate
210	a) T	The director of a clinical laboratory shall not direct more than five moderate or
.211 .212		The director of a clinical laboratory shall not direct more than <u>five moderate or</u> igh complexitythree clinical laboratories, as defined in 42 CFR 493 or blood
213		anks. This limitation does not preclude a laboratory director from serving
214		dditional laboratories as a technical supervisor, technical or clinical consultant,
215		eneral supervisor, or testing personnel consultant, general supervisor, or acting
216	_	irector.
217	G	
218	b) T	The director of a clinical laboratory shall must actively participate in the activities
219	′	nd programs of the clinical laboratory; therefore, attendance of brief duration
220		ufficing only for signature of reports or other nominal administrative duties will
221		ot constitute compliance with Section 6-104 of the Act.
222		F
223	(Source:	Amended at 44 Ill. Reg, effective)
224	`	C
225		SUBPART D: QUALIFICATIONS OF PERSONNEL
226		
227	Section 450.410	General Supervisor
228		
229		rtified) laboratory, the general supervisor shall be accessible to the laboratory to
230	-	telephone, or electronic consultation, and shall meet qualification requirements
.231	<u>in 42 CFR 493,</u>	Subpart M.
232		
233	/	Duties
234		n a licensed laboratory, there shall be at least one qualified director or supervisor
235		n the laboratory premises during all hours in which tests are performed. In the
236		bsence of the director, the supervisor shall supervise technical personnel and
.237		eporting of findings, perform tests requiring special scientific skills and be held
238		esponsible for the proper performance of all laboratory procedures. During
239	p	eriods of time when the laboratory is open for emergency testing only, a director
240	θ	r supervisor is not required to be on the premises provided a qualified
241	ŧ	echnologist (See Section 450.420) performs the emergency tests and the director
242		r supervisor who is responsible for the work reviews and documents the review
243	θ	f the results during the next duty period when the laboratory is open to provide
244	θ	ther than emergency testing or within 24 hours, whichever occurs first. An
245	A	mergency shall be determined by the physician attending the patient, and in
246	θ	rder to clearly indicate an emergency exists, the laboratory request form shall acclude an appropriate designation such as "Stat"

1248					
1249	b)	An ir	idividua	l who meets one of the following qualifications shall qualify as	
1250		general supervisor. These qualifications must be documented on the Department's			
1251		form entitled "Laboratory Personnel Qualifications Appraisal". (See Section			
1252		450.50(c)(3)):			
1253					
1254		1)	The ir	ndividual is a physician licensed to practice medicine in all of its	
1255			brancl	hes or has an earned doctoral degree from an accredited institution in	
1256				lical laboratory science such as microbiology and clinical chemistry	
1257			and st	absequent to graduation has had at least 1 year of full-time	
1258				ience in one of the laboratory specialties in an approved clinical	
1259			labora		
1260					
1261		2)	The ir	ndividual has a Master of Arts or Master of Science degree from an	
1262			accrec	dited institution in a medical laboratory science such as microbiology	
1263			and cl	inical chemistry and subsequent to graduation has had at least 1 year	
1264				l-time laboratory experience in an approved clinical laboratory.	
1265					
1266		3)	The ir	ndividual is qualified as a medical technologist pursuant to the	
1267			provis	sions of Section 450.420. If the individual qualifies as a medical	
1268			techno	ologist because the individual has successfully passed the United	
1269			States	Public Health Service Exam prior to July 1, 1989, the individual has	
1270			either		
1271					
1272			A)	an associate degree or at least 60 semester hours of academic credit	
1273			ŕ	from an accredited institution, including at least 12 semester hours	
1274				in chemistry and biology courses and four years of full-time	
1275				laboratory experience in an approved clinical laboratory; or	
1276					
1277			B)	six years of experience as a medical technologist in an approved	
1278			,	laboratory.	
1279				•	
1280		4)	With	respect to the specialty of diagnostic cytology, qualifies as a	
1281			super	visory cytotechnologist because the individual qualifies as a	
1282			cytote	echnologist under Section 450.430(a), (b) or (c) and has had at least 4	
1283				of full-time experience within the preceding 10 years as a	
1284				echnologist in a laboratory directed by an individual qualified to	
1285				such a laboratory under Section 6-103 of the Act within the	
1286				ding 10 years.	
1287			•		
1288		5)	With	respect to the specialty of genetics, qualifies as a supervisor because	
1289			the in	dividual meets the requirements of subsections (b)(1), (2) or (3)	
1290			above	a minimum of two years of experience, except that the experience	

1291 requirements must be in a genetics laboratory. 1292 1293 Exception to subsections (b) (1), (2), and (3) above c) 1294 An individual serving as general supervisor of a clinical laboratory on September 1295 15, 1970 and having had at least 15 years of pertinent laboratory experience prior to September 15, 1970 may continue to serve as supervisor of said laboratory: 1296 1297 provided, that a minimum of 30 semester hours credit toward a Bachelor's degree 1298 with a chemical, physical or biological science as his major subject shall reduce 1299 the required years of experience by 2 years, with any additional hours further 1300 reducing the required years of experience at the rate of 15 hours for 1 year. 1301 1302 (Source: Amended at 44 Ill. Reg. _____, effective _____) 1303 1304 Section 450.420 Testing Personnel Medical Technologist 1305 1306 A testing personnel candidate shall meet one or more options of the qualification requirements in 1307 42 CFR 493, Subpart M. 1308 1309 An individual who meets one of the following qualifications shall qualify as a a) 1310 technologist. These qualifications must be documented on the Department's form 1311 entitled "Laboratory Personnel Qualifications Appraisal". (See Section 1312 450.50(c)(3)1313 1314 1) The individual has an earned Bachelor's degree in medical technology 1315 from an accredited college or university. 1316 1317 2) The individual has 3 academic years of study (a minimum of 90 semester 1318 hours or equivalent) in an accredited college or university which meets the specific requirement for entrance into, and the successful completion of a 1319 1320 course of training of at least 12 months in, a school of medical technology 1321 accredited by one of the agencies recognized by the U.S. Office of 1322 Education for the accreditation of training programs for medical 1323 technologists, as distinguished from training programs for medical 1324 laboratory technicians. 1325 1326 The individual has an earned Bachelor's degree from an accredited college 3) 1327 or university course of studies which meets all academic requirements for 1328 a in one of the chemical, physical, or biological sciences and in addition at 1329 least 1 year of clinical laboratory experience and/or training in an 1330 approved clinical laboratory in the laboratory field or fields in which the individual performs tests. 1331 1332 1333 4) The individual has completed 3 years (90 Semester hours or equivalent in

1334			quart	er hours) in an accredited college or university with a distribution of
1335				ses as shown below, and, in addition, successful experience and/or
1336			traini	ng covering several fields of medical laboratory work of such length
1337				ess than 1 year), and of such quality that this experience or training
1338				approved clinical laboratory in the laboratory field or fields in which
1339				ndividual performs tests. The specified courses must have included
1340				re and laboratory work. Survey courses are not acceptable.
1341				The second of th
1342			A)	For those whose training was completed prior to September 15,
1343			/	1963: academic training must include at least 24 semester hours in
1344				chemistry and biology courses of which not less than 9 semester
1345				hours must have been in chemistry and must have included at least
1346				6 semester hours in inorganic chemistry, and not less than 12
1347				semester hours must have been in biology courses pertinent to the
1348				medical sciences.
1349				medical sciences.
1350			B)	For those whose training was completed after September 15, 1963:
1351			D)	academic training must include 16 semester hours in chemistry
1351				courses which must have included at least 6 semester hours in
1353				general chemistry and the remaining semester hours in analytical
1354				chemistry, organic chemistry or physical chemistry and which are
1355				acceptable toward a major in chemistry; 16 semester hours in
1356				biology courses which are pertinent to the medical sciences and are
1357				
1358				acceptable toward a major in biological sciences; and 3 semester hours of mathematics.
1356				Hours of mathematics.
	b)	Evac	ntions t	o subsection (a) above
1360 1361	b)	Exce	puons u	o subsection (a) above
		1)	A m . av	waantien to subsection (a) may be made if
1362		1)	An e	xception to subsection (a) may be made if
1363			A >	
1364			A)	The technologist was performing the duties of a medical
1365				technologist on, or within the 5 years preceding July 1, 1966, and
1366			D)	
1367			B)	The technologist has had at least 10 years of pertinent clinical
1368				laboratory experience prior to July 1, 1966, provided, that a
1369				minimum of 30 semester hours of credit toward a bachelor's degree
1370				from an accredited institution with a chemical, physical, or
1371				biological science as his major subject, or 30 semester hours in a
1372				school of medical technology approved in accordance with
1373				subsection (a)(2) shall reduce the required years of experience by 2
1374				years, with any additional hours further reducing the required years
1375				of experience at the rate of 15 hours for 1 year.
1376				

1377		2)	An individual who has successfully passed the United States Public Health
1378			Service exam in order to qualify under Medicare and Medicaid as a
1379			clinical laboratory technologist will be considered to meet the
1380			qualifications for a medical technologist upon submission of
1381			documentation to the Department.
1382			•
1383	(Sour	ce: Ame	ended at 44 Ill. Reg, effective)
1384			
1385	Section 450.	430 Cyt	totechnologist (Repealed)
1386			
1387	An individua	l who m	eets one of the following qualifications shall qualify as a cytotechnologist.
1388	These qualifi	cations 1	must be documented on the Department's form entitled "Laboratory
1389	Personnel Qu	ialificati	ons Appraisal". (See Section 450.50(c)(3)):
1390			
1391	a)	The in	dividual has successfully completed 2 years (60 semester hours of
1392			nic credit) in an accredited college or university with at least 12 semester
1393			in science, 8 hours of which are in biology, and has had 12 months of
1394			g in a school of cytotechnology accredited by one of the agencies
1395			nized by the U.S. Commissioner of Education; or
1396		C	
1397	b)	The in	dividual has successfully completed 2 years (60 semester hours of
1398	,		nic credit) in an accredited college or university with at least 12 semester
1399			in science, 8 hours of which are in biology, and has received 6 months of
1400			training in a school or agency cytotechnology accredited by one of the
1401			liting recognized by the U.S. Commissioner of Education and 6 months of
1402			ne experience in cytotechnology in a laboratory affiliated with the school of
1403 1404			chnology; or
1405	e)	Prior t	o January 1, 1969, the individual has
1406 1407		1)	graduated from high school
1407		1)	graduated from high school
1409		2)	completed 6 months of training in cytotechnology in a laboratory directed
1410		_/	by a physician certified or determined board eligible by the American
1411			Board of Pathology in pathologic anatomy and
1412			Bould of Futilology in putilologic unatomy und
1413		3)	completed 2 years of full time supervised experience in cytotechnology.
1414		3)	completed 2 years of run time supervised experience in cytotechnology.
1415	(Sour	ce: Ren	ealed at 44 Ill. Reg, effective)
1416	(DOLL)	cc. Rep	, oncoure
1417	Section 450	440 Tec	chnician (Repealed)
1418	5000001 450.	1-10 100	American (Acepeance)
1/10	An individuo	l who m	eats one of the following qualifications shall qualify as a technician: These

1420		s must be documented on the Department's form entitled "Laboratory Personnel
1421	Qualification	as Appraisal". (See Section 450.50(c)(3)). Persons employed by a laboratory which
1422		finition of a Class II Laboratory which do not presently have the minimum
1423	qualification	s of a technician may continue to be employed by the laboratory in question until
1424		without meeting the requirements of a technician. After July 1, 1992, all technical
1425	persons perfe	orming laboratory testing must meet the qualifications set forth in this Part.
1426		
1427	a)	Successful completion of 60 semester hours of academic credit including
1428	,	chemistry and biology as well as a structured curriculum in medical laboratory
1429		techniques at an accredited institution or has an associate degree based on a
1430		course of study including those subjects from an accredited institution; or
1431	b)	High school graduate or equivalent and has completed at least 1 year in a
1432	-,	technician training program in a school accredited by an accrediting agency
1433		approved by the U.S. Office of Education; or
1434		approved by the class of Education, or
1435	e)	High school graduate or equivalent and has successfully completed an official
1436	C)	military medical laboratory procedures course of at least 50 weeks duration and
1437		has held the military enlisted occupational specialty of Medical Laboratory
1438		Specialist (Laboratory Technician).
1439		Specialist (Eaboratory Technician).
1440	(Sour	rce: Repealed at 44 Ill. Reg, effective)
1441	(Both	ce. Repetited in 44 III. Reg
1442	Section 450	450 Laboratory Assistant (Repealed)
1443	Section 450	130 Duborutory Assistant (Arepeared)
1444	A laboratory	assistant is an individual who is employed in a laboratory and meets the education
1445		ce requirements set forth by that laboratory director and who functions only under
1446		pervision of a director, supervisor or technologist. These requirements must be
1447		n writing and submitted to the Department with the Department's form entitled
1448		Personnel Qualifications Appraisal" (See Section 450.50(c)(3)).
1449	Laboratory	reisonner Quantications Appraisar (See Section 430.30(c)(3)).
449	(Sour	rce: Repealed at 44 Ill. Reg, effective)
451	(500)	ce. Repealed at 44 III. Reg
452	Section 450	460 Technical Supervisor
1453	Section 430	400 Technical Supervisor
1454	In a licensed	(certified) laboratory, the technical supervisor shall be accessible to the laboratory
1455		n-site, telephone or electronic consultation, and shall meet one or more specific
1456		Exaction requirements under each specialty or subspecialty of service in 42 CFR 493
1457	Subpart M.	ication requirements under each specialty of subspecialty of service in 42 CFR 493
	Subpart IVI.	
1458 1459	(Som	rce: Added at 44 Ill. Reg, effective)
1460	(Soul	.cc. Added at 44 III. Reg, effective
461	Section 450	470 Clinical Consultant
1461 1462	<u> </u>	7/0 Chinea Consultant

(Source	e: Ad	ded at 44 Ill. Reg, effective)
		SUBPART F: OUT OF STATE LABORATORIES
Section 450.6	10 Cr	iteria for Licensure
Clinical labora	atories	located outside of Illinois shall be certified, under CLIA Law, or that state's
		before accepting specimens referred by clinical laboratories located in
a)		is licensure is required if clinical laboratories located outside of this state of the specimens referred by clinical laboratories located in Illinois.
b)	Out-c	of-state laboratories shall:
	1)	Apply for an Illinois license in the same manner as facilities located in this
		State and pay the same licensee fees.
	2)	Comply with all standards applicable to laboratories located in Illinois. In
	2)	cases in which the standards of practice permitted in the state in which the
		laboratory is located are not in accordance with these standards, the out-
		of-state laboratories shall comply with these Illinois standards when serving licensed physicians, dentists, hospitals, blood banks, or clinical
		laboratories located in Illinois which are required to have a license or
		permit.
	2)	Cubarit analy garante as many har garanteed in alleding but not limited to
	3)	Submit such reports as may be required, including but not limited to periodic reports of Illinois laboratories or blood banks referring specimens
		to the out-of-state laboratory.
	4)	Accept evaluation specimens referred by the Illinois Department of Public
		Health or participate in evaluation of specimens in programs approved by
		the Department.
	5)	If located in a state which licenses clinical laboratories, must hold a
		currently valid state license.
	6)	Submit with each state license application, a copy of the laboratory's
		current license to conduct interstate laboratory services under the Federal
		Clinical Laboratory Improvement Amendments of 1988 (P.L. 100-578, effective October 31, 1988). Such license shall be used by the Department

1506		to determine compliance with this Act.
1507	48	
1508	(Sour	ce: Amended at 44 Ill. Reg, effective)
1509		
1510		SUBPART G: PROFICIENCY SURVEY PROGRAM AND
1511		INSPECTION OF FACILITIES
1512	G 4=0.	
1513	Section 450.	710 Inspections
1514		All 1' 111 A CTTAT 1 1'
1515	a)	All clinical laboratories required to be certified under CLIA Lawhave a license of
1516		permit shall be open to inspection by representatives of the Department at all
1517		reasonable times. The premises and operation of all clinical laboratories shall be
1518		inspected to study and evaluate the effect of the location, operation, supervision
1519 1520		and procedures of such facilities on the health and safety of the people of this
1520 1521		state. These inspections will be made at such time as may from time to time be
1521		determined by the Department, and may be announced or unannounced. These inspections may include on site review of records and reports pertaining to the
1523		technical operations of the laboratory.
1523 1524		teenmear operations or the laboratory.
1525	b)	The Department may submit forms, such as check lists, to be completed by the
1525	U)	director of the laboratory in advance of inspection. These forms may include
1527		questions relating to the construction, sanitation, equipment, procedures, and
1528		records which will be reviewed by the Department and will assist it in making
1529		inspections to determine compliance with the Act and this Part.
1530		inspections to determine compitance with the 7 et and this 1 art.
1531	(Sour	ce: Amended at 44 Ill. Reg, effective)
1532	`	<u> </u>
1533	Section 450.	720 Proficiency Survey Program
1534		·
1535	Each laborate	ory shall enroll in a proficiency testing (PT) program that meets the criteria of 42
1536	CFR 493, Su	bparts H, I, K and R. The laboratory shall enroll in an approved program or
1537		each of the non-waived specialties and subspecialties for which it seeks
1538	certification,	and shall test the samples in the same manner as patients' specimens.
1539		
1540	a)	The Department shall require the "demonstration of proficiency" in the
1541		performance of each test offered by licensed or permitted clinical laboratories by
1542		means of State operated or State approved proficiency testing programs. The
1543		Department may exclude some specific tests from this requirement.
1544		
1545	b)	Requirements for Testing Service Approval
1546		
1547		1) The State approved proficiency testing service must cover all clinical
1548		laboratory and anatomical pathology specialties and subspecialties in

1549		which the laboratory performs tests as they are made available and are
1550		proven feasible for proficiency testing. One or more proficiency testing
1551		programs can be utilized to address all tests conducted by a laboratory.
1552		
1553		2) The approved proficiency testing service must provide to the Department
1554		an annual list of subscribers among Illinois laboratories authorizing the
1555		proficiency testing service to report their proficiency test results to the
1556		Department.
1557		
1558		3) The approved proficiency testing service must supply exception reports
1559		(cumulative survey management reports cumulative deviancy reports)
1560		covering at least the immediately previous two years of testing and
1561		documenting the unsatisfactory results during that minimum two year
1562		period. This report must be continuously updated with each new testing
1563		period and must be made available to both the participating laboratory and
1564		to the Department after each testing period.
1565		
1566		4) The approved proficiency testing service must provide at least the
1567		following statistical parameters: mean or median, standard deviation or
1568		coefficient of variation, and some discussion and/or indication of accuracy
1569		and precision.
1570		
1571		5) The approved proficiency testing service must document, in writing, the
1572		bases for establishing acceptable limits of performance. This
1573		documentation must be supplied to the Department and to each
1574		participating laboratory at least annually and must cover each test for
1575		which proficiency testing is provided. The yearly revision must include
1576		all changes made in the criteria for acceptable performance which are to
1577		prevail for the ensuing year.
1578		
1579	e)	A list of the State-approved proficiency testing programs may be obtained from
1580	,	the Department.
1581		
1582	d)	The costs of such State-approved proficiency testing shall be borne by the
1583		laboratory.
1584		
1585	e)	The laboratory shall keep on file a copy of the results of proficiency testing for
1586	-/	review by the State laboratory evaluator.
1587		
1588	f)	Requirements for Laboratory Testing
1589	-/	1
1590		1) The participating laboratory must test applicable materials each time they
1591		are distributed by the approved proficiency testing service according to a

1592		sched	lule approved by the Department.
1593			
1594	2)	Thos	e procedures performed by the laboratory for which test materials are
1595		provi	ded by the approved proficiency testing service and which are not
1596			ded by the Department from the "demonstration of proficiency"
1597		requi	rement must be proficiency tested by the participating laboratory
1598			time test materials are received.
1599			
1600	3)	The p	participating laboratory must authorize the approved proficiency
1601			eg service to report proficiency test results to the Department.
1602			
1603	4)	The r	participating laboratory must test applicable materials only in the
1604		labor	atory to which the license and the proficiency testing requirement
1605			es using personnel and equipment used in that facility in providing
1606		servi	
1607			
1608	5)	A lab	poratory shall be required to discontinue providing a service in a
1609	,		edure or category of procedures (hematology, chemistry,
1610			riology-mycology, parasitology, immunology-serology,
1611			unohematology, etc.) if:
1612			,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
1613		A)	For three consecutive testing periods the laboratory fails to report
1614		/	on test materials received for procedures for which the laboratory
1615			is required to be proficiency tested; or
1616			is required to be promisedly tosted, or
1617		B)	For three consecutive testing periods the laboratory demonstrates
1618		2)	unsatisfactory performance in a procedure or category of
1619			procedures. A determination of satisfactory performance for a
1620			procedure for a testing period shall be based upon all results being
1621			within acceptable limits established by the proficiency testing
1622			service for that procedure and approved by the Department. A
1623			determination of satisfactory performance for a category of
1624			procedures shall be based upon 75% or more of the results in that
1625			category over three consecutive testing periods being within
1626			acceptable limits established by the Department.
1627			acceptable mints established by the Department.
1628	6)	Δlab	poratory whose services have been disapproved because of
1629	0)		isfactory performance shall be reapproved by the Department to
1630			de these services after meeting one of the following conditions,
1631			
1632			ded that proficiency testing is the only problem preventing
1632 1633		reapp	oroval.
1633 1634		A)	The laboratory results for an unsatisfactory discontinued procedur
10.74		/ \ 	THE PARACHORY RESILIE FOR AN INICATE ACCOMPANIED MYOCACH

1635		shall	be within acceptable limits established by the proficiency
1636		testin	g service for two consecutive testing periods subsequent to
1637		the te	esting periods which resulted in the discontinuance of the
1638			dure. The laboratory results for a disapproved category of
1639			edures shall have 75% or more of the results within acceptable
1640		-	s established by the proficiency testing service for two
1641			ecutive testing periods subsequent to the testing periods which
1642			ted in discontinuance of the category of procedures.
1643		10541	sed in discontinuation of the eutogory of procedures.
1644	B)	On-si	te-Testing
1645	2)	On si	ine Tobang
1646		i)	The laboratory director may request the Department to
1647		1)	provide proficiency testing specimens for purposes of
1648			retesting. The cost of such proficiency testing specimens
1649			shall be borne wholly by the laboratory. The Department
1650			shall ship or cause to be shipped, hand carry or otherwise
1651			convey to the laboratory such proficiency testing specimen
1652			convey to the laboratory such proficiency testing specimens within three weeks after receipt of such request. The
1653			Department shall provide on on site visit by a laboratory
1654			Department shall provide an on site visit by a laboratory
			evaluator for the purpose of determining deficiency
1655			correction.
1656		::1	Successful analysis (1000) of anaitic analysis on 750/ of
1657		ii)	Successful analysis (100% of specific analysis or 75% of
1658			the results of a category are within acceptable limits as
1659			established by the testing service) shall be based upon test
1660			results of specimens similar in number and purpose to those
1661			normally received by the laboratory where performance has
1662			been judged unsatisfactory.
1663		•••>	
1664		iii)	Successful analysis and site visit findings shall be used to
1665			reapprove either a category of procedures or a given
1666			procedure.
1667			
1668			e or permit may be denied for failure to maintain an
1669		tandard	of proficiency in the program and services provided by a
1670	laboratory.		
1671			
1672	(Source: Amended	at 44 Ill	. Reg, effective)
1673			
1674	SUBPAR		PECIAL REQUIREMENTS PERTAINING
1675		ТО	BLOOD BANKS (Repealed)
1676			
1677	Section 450.810 General	Repeal	e d)

1678 1679 Blood banks operating in Illinois shall be licensed by the FDA under 21 CFR 600, 601, 606, 607, 1680 610, 630 and 640. 1681 1682 (Source: Former Section repealed at 13 Ill. Reg. 11573, effective September 1, 1989; new Section added at 44 Ill. Reg. _____, effective _____) 1683 1684 1685 SUBPART J: RECORDS AND REPORTS 1686 1687 Section 450.1010 Necessary Records 1688 1689 Complete records in regard to each specimen examined shall be kept on file in the a) laboratory for not less than five years. The Such records shall contain: 1690 1691 1692 1) Laboratory number or other identification of the specimen. 1693 1694 2) The name of the person from whom the specimen was taken, except in 1695 cases of anonymous HIV testing or of anonymous or coded premarital syphilis testing. The names and addresses of persons who have chosen to 1696 1697 have HIV testing done anonymously may not be recorded in the files, except that any existing records referring to testing done before anonymity 1698 was chosen may be retained without linkage to the anonymous testing. 1699 1700 1701 3) The name of the licensed physician or other authorized person, clinical 1702 laboratory, or blood bank submitting the specimen. 1703 1704 4) The date the specimen was collected and the date the specimen was 1705 received in the laboratory. 1706 1707 5) When a specimen is forwarded to another clinical laboratory for tests, the name, the date when the specimen was forwarded to the such laboratory, 1708 the date it was tested, and the date the report of the findings of the test was 1709 1710 received from thesuch laboratory. 1711 1712 In case the specimen is an unsatisfactory specimen, the condition of the 6) 1713 specimen when received. 1714 1715 7) The types and numbers of tests performed annually. 1716 1717 8) The results of the test conducted by the laboratory, the method used, the 1718 signature of the examiner. 1719 1720 9) Clinical laboratory test results may be reported or transmitted to: Results

1721				oratory tests are to be reported to the referring laboratory and/or
1722			practi	tioner in accordance with Sections 3-101, 7-102, and 7-103 of the
1723			Act.	
1724				
1725			<u>A)</u>	The licensed physician, the patient if requested, or other
1726				authorized person who requested the test, their designee, or both;
1727				
1728			<u>B)</u>	Any health care provider who is providing treatment to the patient;
1729				<u>or</u>
1730				
1731			<u>C)</u>	An electronic health information exchange for the purposes of
1732				transmitting, using, or disclosing clinical laboratory test results in
1733				any manner required or permitted by HIPAA.
1734				
1735		<u>10)</u>	No in	terpretation, diagnosis, prognosis, or suggested treatment shall
1736			appea	ar on the laboratory report form, except that a report made by a
1737			physic	cian licensed to practice medicine in Illinois, a dentist licensed in
1738			Illino	is, or an optometrist licensed in Illinois may include that
1739			inforn	nation.
1740				
1741		<u>11)</u>	Nothi	ng in this Part prohibits the sharing of information as authorized in
1742			Section	on 2.1 of the Department of Public Health Act. (Section 7-102 of the
1743			Act)	
1744				
1745	b)	Repor	ts to be	submitted to the Department.
1746		A labo	oratory	shall submit reports containing-such information and data
1747		conce	rning it	s technical operations, as may be requested by the Department.
1748		These	The De	partment may require that such reports <u>shall</u> be notarized and signed
1749		by the	owner	and director of the laboratory, if these are different.
1750				
1751	(Sour	rce: Am	ended a	at 44 Ill. Reg, effective)
1752				
1753				SUBPART K: QUALITY CONTROL
1754				
1755	Section 450.	.1150 Q	uality (Control System Methodologies
1756				
1757	a)	Hema	tology	
1758				
1759		1)	Manu	al Procedures
1760				
1761			A)	Each procedure shall be checked or recalibrated each day of use
1762			•	with standards (calibrators) or reference materials covering the
1763				range of expected values. See Section 450.520 for checking
				-

dilutors and samplers.

- B) Hemoglobin methodology shall be calibrated monthly with standards that cover at least three concentrations and a zero point.
- C) Hematocrit Optimum packing time of microhematocrit centrifuges shall be determined before being placed into use and after major adjustments or repairs. The speed of the microhematocrit centrifuge shall be checked monthly. Tolerance limits shall be established. Timer checks shall be performed monthly. Tolerance limits shall be established.
- D) Red and White cell counts The hemocytometer counting chamber and coverslip shall be maintained in a condition that does not interfere with cell recognition or the volume of the chamber. Coverslips certified by the Bureau of Biological Standards shall be used. Counts shall be performed with certified pipettes or pipettors whose accuracy has been determined by the manufacturer.
- E) Platelet counts Manual platelet counts shall be performed by counting both sides of the chamber. Tolerance limits shall be established. A procedure to compare platelet results with the differential blood film shall be established.
- F) Differential Leukocyte count Blood smears shall be prepared and stained by a method which produces smears in which morphologic cell features can be evaluated. Cellular morphology shall be examined and platelets estimated routinely with the differential count.

2) Automated Procedures

- A) Particle Counting and Hemoglobin
 - i) Calibration techniques shall follow the manufacturer's specifications.
 - ii) The director shall establish criteria for high and low counts and determine the policy for verification. Tolerance limits shall be established for duplicate testing.
 - iii) Background counts shall be performed daily on diluent and lysing agents.

1807					
1808				iv)	Reference materials shall be used each, or after each run to
1809					assess precision.
1810					
1811				v)	Each procedure shall be checked or recalibrated each 8
1812					hours, if the instrument is used during the 8 hour period,
1813					with standards (calibrators) or reference materials covering
1814					the range of expected values.
1815					
1816			B)	Diffe	rential counts
1817					
1818				i)	The manufacturer's specifications shall be followed with
1819					respect to operation, calibration, and the use of reference
1820					materials.
1821					
1822				ii)	The director shall establish a policy for the review of all
1823					abnormal differentials that indicate an abnormal cellular,
1824					morphology or abnormal platelet enumeration.
1825					1
1826		3)	Coag	ulation	studies
1827		,	C		
1828			A)	Two	levels of reference materials for prothrombin and or partial
1829			,		aboplastin times shall be used during each 8 hours when the
1830					iment is used, Action limits shall be established.
1831					
1832			B)	If ava	ailable commercially, two levels of reference materials shall
1833			,		cluded in each run for all other coagulation procedures.
1834					nt specimens shall be performed in duplicate and tolerance
1835					s established.
1836					
1837	b)	Chem	nistrv		
1838	- /		•	450.112	0 for general quality control requirements. See Section
1839					g dilutors and samplers.
1840					8
1841		1)	Manı	ıal-Auto	omated procedures which use a Spectrophotometer or
1842		1)		meter	sinated procedures which use a specific photometer of
1843			111000	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
1844			A)	Calib	ration of the optical component of each instrument shall be
1845			/		in accordance with the instrument manufacturer's
1846					actions.
1847				1115616	
1848			B)	Each	procedure shall be recalibrated at least every three months or
1849			_,		frequently in accordance with the following:
/				111010	

concentrations (calibrator) (unless the instrument manufacturer specifies that 3 calibrators are not necessary to determine procedure in linearity and calibration over the reportable range) including one at the highest level of the reportable range and one near the threshold (cutoff). Procedures which are non-linear over the reportable range shall include (unless the instrument manufacturer specifies that procedure calibration over the reportable range shall include (unless the instrument manufacturer specifies that procedure calibration over the reportable range can be accomplished in another manner) a minimum of 5 standard concentrations (calibrator). The procedure is recalibrated when major instrument maintenance has been performed. The procedure is recalibrated when major instrument maintenance has been performed. The procedure is recalibrated when the quality control number is changed. The procedure is recalibrated when the quality control program reflects an unusual trend or the controls fall outside acceptable limits. The procedure is recalibrated when the quality control program reflects an unusual trend or the controls fall outside acceptable limits. C) At a minimum, one reference material and one calibrator or two reference materials with different concentrations shall be used for each analyte in each run of unknown specimens, except, when prepackaged reagent analyzers are used, one reference material and one calibrator or two reference materials with different concentrations shall be used for the analyzer is used for that analyte. Atomic Absorption Flame Photometers A) The atomization rate shall be checked each day of use. B) Each run of unknown specimens shall include two levels of reference materials.					
concentrations (calibrator) (unless the instrument manufacturer specifies that 3 calibrators are not necessary to determine procedure in linearity and calibration over the reportable range) including one at the highest level of the reportable range and one near the threshold (cutoff). Procedures which are non-linear over the reportable range shall include (unless the instrument manufacturer specifies that procedure calibration over the reportable range can be accomplished in another manner) a minimum of 5 standard concentrations (calibrator). The procedure is recalibrated when major instrument maintenance has been performed. The procedure is recalibrated when major instrument maintenance has been performed. The procedure is recalibrated when the quality control number is changed. The procedure is recalibrated when the quality control program reflects an unusual trend or the controls fall outside acceptable limits. The procedure is recalibrated when the quality control program reflects an unusual trend or the controls fall outside acceptable limits. C) At a minimum, one reference material and one calibrator or two reference materials with different concentrations shall be used for each analyte in each run of unknown specimens, except, when prepackaged reagent analyzers are used, one reference material and one calibrator or two reference materials with different concentrations shall be used for the analyzer is used for that analyte. A) The atomization rate shall be checked each day of use. B) Each run of unknown specimens shall include two levels of reference materials. C) Calibration and operation techniques shall follow the manufacturer's specifications.	1850				
manufacturer specifies that 3 calibrators are not necessary to determine procedure in linearity and calibration over the reportable range) including one at the highest level of the reportable range and one near the threshold (cutoff). Procedures which are non-linear over the reportable range shall include (unless the instrument manufacturer specifies that procedure calibration over the reportable range can be accomplished in another manner) a minimum of 5 standard concentrations (calibrator). The procedure is recalibrated when major instrument maintenance has been performed. iii) The procedure is recalibrated when major instrument maintenance has been performed. iv) The procedure is recalibrated when a reagent lot number is changed. v) The procedure is recalibrated when the quality control program reflects an unusual trend or the controls fall outside acceptable limits. c) At a minimum, one reference material and one calibrator or two reference materials with different concentrations shall be used for each analyte in each run of unknown specimens, except, when prepackaged reagent analyzers are used, one reference material and one calibrator or two reference materials with different concentrations shall be used for that analyte. Atomic Absorption Flame Photometers A) The atomization rate shall be checked each day of use. Each run of unknown specimens shall include two levels of reference materials.	1851			i)	Procedures which are linear shall include at least 3 standard
to determine procedure in linearity and calibration over the reportable range) including one at the highest level of the reportable range and one near the threshold (cutoff). Procedures which are non-linear over the reportable range shall include (unless the instrument manufacturer specifies that procedure calibration over the reportable range shall include (unless the instrument manufacturer specifies that procedure calibration over the reportable range can be accomplished in another manner) a minimum of 5 standard concentrations (calibrator). The procedure is recalibrated when major instrument maintenance has been performed. The procedure is recalibrated in accordance with the manufacturer's recommendations and when a reagent lot number is changed. The procedure is recalibrated when the quality control program reflects an unusual trend or the controls fall outside acceptable limits. The procedure is recalibrated when the quality control program reflects an unusual trend or the controls fall outside acceptable limits. C	1852				concentrations (calibrator) (unless the instrument
reportable range) including one at the highest level of the reportable range and one near the threshold (cutoff). Standard	1853				manufacturer specifies that 3 calibrators are not necessary
reportable range and one near the threshold (cutoff). 1857 1858 1859 1859 1860 1861 1861 1862 1862 1863 1864 1865 1866 1866 1867 190 17he procedure is recalibrated when major instrument manufacturer's pecifies that procedure calibrated when major instrument maintenance has been performed. 1866 1867 190 17he procedure is recalibrated when major instrument maintenance has been performed. 1868 1869 1870 1871 1871 190 17he procedure is recalibrated in accordance with the manufacturer's recommendations and when a reagent lot number is changed. 1871 1871 190 17he procedure is recalibrated when the quality control program reflects an unusual trend or the controls fall outside acceptable limits. 1874 1875 1876 1877 1878 1879 1879 1879 1879 1879 1870 1870 1870 1871 1871 1871 20 21 21 22 33 34 34 34 35 35 36 36 37 37 38 38 38 38 39 40 41 38 40 41 41 41 41 41 41 41 41 41 41 41 41 41	1854				to determine procedure in linearity and calibration over the
reportable range and one near the threshold (cutoff). 1857 1858 1859 1859 1860 1860 1861 1861 1862 1862 1863 1864 1865 1865 1866 1866 1866 1867 190 100 100 100 100 100 100 100 100 100	1855				reportable range) including one at the highest level of the
1858 1859 1859 1859 1860 1860 1860 1861 1861 1862 1862 1862 1863 1864 1865 1866 1866 1866 1866 1867 197 1986 1868 1869 1997 1998 1870 1987 1988 1870 1987 1988 1877 1998 1877 200 1877 200 1877 200 1877 200 1877 200 1877 200 1877 200 1878 200 200 200 200 200 200 200 200 200 20	1856				
shall include (unless the instrument manufacturer specifies that procedure calibration over the reportable range can be accomplished in another manner) a minimum of 5 standard concentrations (calibrator). The procedure is recalibrated when major instrument maintenance has been performed. The procedure is recalibrated in accordance with the manufacturer's recommendations and when a reagent lot number is changed. The procedure is recalibrated in accordance with the manufacturer's recommendations and when a reagent lot number is changed. The procedure is recalibrated when the quality control program reflects an unusual trend or the controls fall outside acceptable limits. C) At a minimum, one reference material and one calibrator or two reference materials with different concentrations shall be used for each analyte in each run of unknown specimens, except, when prepackaged reagent analyzers are used, one reference material and one calibrator or two reference materials with different concentrations shall be used once in each 24 hour period in which the analyzer is used for that analyte. A) The atomization rate shall be checked each day of use. B) Each run of unknown specimens shall include two levels of reference materials. B) Each run of unknown specimens shall follow the manufacturer's specifications.	1857				
that procedure calibration over the reportable range can be accomplished in another manner) a minimum of 5 standard concentrations (calibrator). 1862	1858			ii)	Procedures which are non-linear over the reportable range
accomplished in another manner) a minimum of 5 standard concentrations (calibrator). The procedure is recalibrated when major instrument maintenance has been performed. iii) The procedure is recalibrated in accordance with the maintenance has been performed. iv) The procedure is recalibrated in accordance with the manufacturer's recommendations and when a reagent lot number is changed. v) The procedure is recalibrated when the quality control program reflects an unusual trend or the controls fall outside acceptable limits. C) At a minimum, one reference material and one calibrator or two reference materials with different concentrations shall be used for each analyte in each run of unknown specimens, except, when prepackaged reagent analyzers are used, one reference material and one calibrator or two reference materials with different concentrations shall be used once in each 24 hour period in which the analyzer is used for that analyte. A) The atomization rate shall be checked each day of use. B) Each run of unknown specimens shall include two levels of reference materials. B) Each run of unknown specimens shall follow the manufacturer's specifications.	1859				shall include (unless the instrument manufacturer specifies
accomplished in another manner) a minimum of 5 standard concentrations (calibrator). The procedure is recalibrated when major instrument maintenance has been performed. The procedure is recalibrated in accordance with the maintenance has been performed. The procedure is recalibrated in accordance with the manufacturer's recommendations and when a reagent lot number is changed. The procedure is recalibrated when the quality control program reflects an unusual trend or the controls fall outside acceptable limits. The procedure is recalibrated when the quality control program reflects an unusual trend or the controls fall outside acceptable limits. The procedure is recalibrated when the quality control program reflects an unusual trend or the controls fall outside acceptable limits. The procedure is recalibrated in accordance with the manusual trend or the controls fall outside acceptable limits. The procedure is recalibrated when major instrument maintenance has been performed. The procedure is recalibrated in accordance with the manusual trend or two reagent lot number is changed. The procedure is recalibrated when major instrument maintenance has been performed. The procedure is recalibrated in accordance with the maintenance has been performed. The procedure is recalibrated when the quality control in the program reflects an unusual trend or the controls fall outside acceptable limits. The procedure is recalibrated when the maintenance has been performed. The procedure is recalibrated when the quality control in the maintenance has been performed. The procedure is recalibrated when the maintenance has been performed. The procedure is recalibrated when the controls fall outside acceptable limits. The procedure is recalibrated when the maintenance has been performed. The procedure is recalibrated when the quality control program reflects an unusual trend or the controls fall outside acceptable limits.	1860				that procedure calibration over the reportable range can be
1863 1864 1865 1866 1866 1866 1866 1867 187 1888 1888	1861				
1864 1865 1866 1866 1867 190 190 190 1870 1871 1872 1873 1874 1875 1876 1876 1877 291 201 201 201 201 201 201 201 201 201 20	1862				concentrations (calibrator).
maintenance has been performed. iv) The procedure is recalibrated in accordance with the manufacturer's recommendations and when a reagent lot number is changed. v) The procedure is recalibrated when the quality control program reflects an unusual trend or the controls fall outside acceptable limits. C) At a minimum, one reference material and one calibrator or two reference materials with different concentrations shall be used for each analyte in each run of unknown specimens, except, when prepackaged reagent analyzers are used, one reference material and one calibrator or two reference materials with different concentrations shall be used for each analyte in each run of unknown specimens, except, when prepackaged reagent analyzers are used, one reference material and one calibrator or two reference materials with different concentrations shall be used once in each 24 hour period in which the analyzer is used for that analyte. Atomic Absorption Flame Photometers A) The atomization rate shall be checked each day of use. B) Each run of unknown specimens shall include two levels of reference materials. C) Calibration and operation techniques shall follow the manufacturer's specifications.	1863				
iv) The procedure is recalibrated in accordance with the manufacturer's recommendations and when a reagent lot number is changed. v) The procedure is recalibrated when the quality control program reflects an unusual trend or the controls fall outside acceptable limits. C) At a minimum, one reference material and one calibrator or two reference materials with different concentrations shall be used for each analyte in each run of unknown specimens, except, when prepackaged reagent analyzers are used, one reference material and one calibrator or two reference materials with different concentrations shall be used for each analyte in each run of unknown specimens, except, when prepackaged reagent analyzers are used, one reference material and one calibrator or two reference materials with different concentrations shall be used once in each 24 hour period in which the analyzer is used for that analyte. Atomic Absorption Flame Photometers A) The atomization rate shall be checked each day of use. B) Each run of unknown specimens shall include two levels of reference materials. C) Calibration and operation techniques shall follow the manufacturer's specifications.	1864			iii)	The procedure is recalibrated when major instrument
iv) The procedure is recalibrated in accordance with the manufacturer's recommendations and when a reagent lot number is changed. v) The procedure is recalibrated when the quality control program reflects an unusual trend or the controls fall outside acceptable limits. C) At a minimum, one reference material and one calibrator or two reference materials with different concentrations shall be used for each analyte in each run of unknown specimens, except, when prepackaged reagent analyzers are used, one reference material and one calibrator or two reference materials with different concentrations shall be used for each analyte in each sall be used one calibrator or two reference materials with different concentrations shall be used for that analyzer is used for that analyte. Atomic Absorption Flame Photometers A) The atomization rate shall be checked each day of use. B) Each run of unknown specimens shall include two levels of reference materials. B) Each run of unknown specimens shall follow the manufacturer's specifications.	1865				maintenance has been performed.
manufacturer's recommendations and when a reagent lot number is changed. v) The procedure is recalibrated when the quality control program reflects an unusual trend or the controls fall outside acceptable limits. C) At a minimum, one reference material and one calibrator or two reference materials with different concentrations shall be used for each analyte in each run of unknown specimens, except, when prepackaged reagent analyzers are used, one reference material and one calibrator or two reference materials with different concentrations shall be used for each analyte in each run of unknown specimens, except, when prepackaged reagent analyzers are used, one reference material and one calibrator or two reference materials with different concentrations shall be used once in each 24 hour period in which the analyzer is used for that analyte. Atomic Absorption Flame Photometers A) The atomization rate shall be checked each day of use. B) Each run of unknown specimens shall include two levels of reference materials. C) Calibration and operation techniques shall follow the manufacturer's specifications.	1866				
number is changed. v) The procedure is recalibrated when the quality control program reflects an unusual trend or the controls fall outside acceptable limits. C) At a minimum, one reference material and one calibrator or two reference materials with different concentrations shall be used for each analyte in each run of unknown specimens, except, when prepackaged reagent analyzers are used, one reference material and one calibrator or two reference materials with different concentrations shall be used for each analyte in each run of unknown specimens, except, when prepackaged reagent analyzers are used, one reference material and one calibrator or two reference materials with different concentrations shall be used once in each 24 hour period in which the analyzer is used for that analyte. Atomic Absorption Flame Photometers A) The atomization rate shall be checked each day of use. B) Each run of unknown specimens shall include two levels of reference materials. B) Each run of unknown specimens shall follow the manufacturer's specifications.	1867			iv)	The procedure is recalibrated in accordance with the
1870 1871 1872 1873 1874 1875 1876 1877 1876 1877 1877 1878 1878 1879 1879 1879 1879	1868				manufacturer's recommendations and when a reagent lot
v) The procedure is recalibrated when the quality control program reflects an unusual trend or the controls fall outside acceptable limits. C) At a minimum, one reference material and one calibrator or two reference materials with different concentrations shall be used for each analyte in each run of unknown specimens, except, when prepackaged reagent analyzers are used, one reference material and one calibrator or two reference materials with different concentrations shall be used for the analyzer is used for that analyte. Atomic Absorption Flame Photometers A) The atomization rate shall be checked each day of use. B) Each run of unknown specimens shall include two levels of reference materials. C) Calibration and operation techniques shall follow the manufacturer's specifications.	1869				number is changed.
program reflects an unusual trend or the controls fall outside acceptable limits. C) At a minimum, one reference material and one calibrator or two reference materials with different concentrations shall be used for each analyte in each run of unknown specimens, except, when prepackaged reagent analyzers are used, one reference material and one calibrator or two reference materials with different concentrations shall be used once in each 24 hour period in which the analyzer is used for that analyte. Atomic Absorption Flame Photometers A) The atomization rate shall be checked each day of use. B) Each run of unknown specimens shall include two levels of reference materials. C) Calibration and operation techniques shall follow the manufacturer's specifications.	1870				
outside acceptable limits. Outside acceptable limits. C) At a minimum, one reference material and one calibrator or two reference materials with different concentrations shall be used for each analyte in each run of unknown specimens, except, when prepackaged reagent analyzers are used, one reference material and one calibrator or two reference materials with different concentrations shall be used once in each 24 hour period in which the analyzer is used for that analyte. Atomic Absorption Flame Photometers A) The atomization rate shall be checked each day of use. B) Each run of unknown specimens shall include two levels of reference materials. C) Calibration and operation techniques shall follow the manufacturer's specifications.	1871			v)	The procedure is recalibrated when the quality control
C) At a minimum, one reference material and one calibrator or two reference materials with different concentrations shall be used for each analyte in each run of unknown specimens, except, when prepackaged reagent analyzers are used, one reference material and one calibrator or two reference materials with different concentrations shall be used once in each 24 hour period in which the analyzer is used for that analyte. Atomic Absorption Flame Photometers A) The atomization rate shall be checked each day of use. B) Each run of unknown specimens shall include two levels of reference materials. C) Calibration and operation techniques shall follow the manufacturer's specifications.	1872				program reflects an unusual trend or the controls fall
C) At a minimum, one reference material and one calibrator or two reference materials with different concentrations shall be used for each analyte in each run of unknown specimens, except, when prepackaged reagent analyzers are used, one reference material and one calibrator or two reference materials with different concentrations shall be used once in each 24 hour period in which the analyzer is used for that analyte. 1882 1883 2) Atomic Absorption Flame Photometers A) The atomization rate shall be checked each day of use. B) Each run of unknown specimens shall include two levels of reference materials. C) Calibration and operation techniques shall follow the manufacturer's specifications.	1873				outside acceptable limits.
reference materials with different concentrations shall be used for each analyte in each run of unknown specimens, except, when prepackaged reagent analyzers are used, one reference material and one calibrator or two reference materials with different concentrations shall be used once in each 24 hour period in which the analyzer is used for that analyte. 2) Atomic Absorption Flame Photometers A) The atomization rate shall be checked each day of use. B) Each run of unknown specimens shall include two levels of reference materials. C) Calibration and operation techniques shall follow the manufacturer's specifications.	1874				
each analyte in each run of unknown specimens, except, when prepackaged reagent analyzers are used, one reference material and one calibrator or two reference materials with different concentrations shall be used once in each 24 hour period in which the analyzer is used for that analyte. Atomic Absorption Flame Photometers A) The atomization rate shall be checked each day of use. B) Each run of unknown specimens shall include two levels of reference materials. B) Each run of peration techniques shall follow the manufacturer's specifications.	1875		C)	At a m	ninimum, one reference material and one calibrator or two
prepackaged reagent analyzers are used, one reference material and one calibrator or two reference materials with different concentrations shall be used once in each 24 hour period in which the analyzer is used for that analyte. Atomic Absorption Flame Photometers A) The atomization rate shall be checked each day of use. B) Each run of unknown specimens shall include two levels of reference materials. B) Each run of unknown specimens shall follow the manufacturer's specifications.	1876			referei	nce materials with different concentrations shall be used for
one calibrator or two reference materials with different concentrations shall be used once in each 24 hour period in which the analyzer is used for that analyte. Atomic Absorption Flame Photometers A) The atomization rate shall be checked each day of use. B) Each run of unknown specimens shall include two levels of reference materials. B) Each run of unknown specimens shall follow the manufacturer's specifications.	1877			each a	nalyte in each run of unknown specimens, except, when
concentrations shall be used once in each 24 hour period in which the analyzer is used for that analyte. 1882 1883 2) Atomic Absorption Flame Photometers 1884 1885 A) The atomization rate shall be checked each day of use. 1886 1887 B) Each run of unknown specimens shall include two levels of reference materials. C) Calibration and operation techniques shall follow the manufacturer's specifications.	1878			prepac	kaged reagent analyzers are used, one reference material and
the analyzer is used for that analyte. 1882 1883 2) Atomic Absorption Flame Photometers 1884 1885 A) The atomization rate shall be checked each day of use. 1886 1887 B) Each run of unknown specimens shall include two levels of reference materials. 1889 1890 C) Calibration and operation techniques shall follow the manufacturer's specifications.	1879			one ca	librator or two reference materials with different
1882 1883 2) Atomic Absorption Flame Photometers 1884 1885 A) The atomization rate shall be checked each day of use. 1886 1887 B) Each run of unknown specimens shall include two levels of reference materials. 1889 1890 C) Calibration and operation techniques shall follow the manufacturer's specifications.	1880			concei	ntrations shall be used once in each 24 hour period in which
Atomic Absorption Flame Photometers A) The atomization rate shall be checked each day of use. B) Each run of unknown specimens shall include two levels of reference materials. C) Calibration and operation techniques shall follow the manufacturer's specifications.	1881			the an	alyzer is used for that analyte.
1884 1885 A) The atomization rate shall be checked each day of use. 1886 1887 B) Each run of unknown specimens shall include two levels of reference materials. 1889 1890 C) Calibration and operation techniques shall follow the manufacturer's specifications.	1882				
A) The atomization rate shall be checked each day of use. B) Each run of unknown specimens shall include two levels of reference materials. C) Calibration and operation techniques shall follow the manufacturer's specifications.	1883	2)	Atomi	ic Absor	ption Flame Photometers
B) Each run of unknown specimens shall include two levels of reference materials. C) Calibration and operation techniques shall follow the manufacturer's specifications.	1884				
B) Each run of unknown specimens shall include two levels of reference materials. 1889 C) Calibration and operation techniques shall follow the manufacturer's specifications.	1885		A)	The at	omization rate shall be checked each day of use.
reference materials. 1889 C) Calibration and operation techniques shall follow the manufacturer's specifications.	1886				
1889 C) Calibration and operation techniques shall follow the manufacturer's specifications.	1887		B)	Each r	un of unknown specimens shall include two levels of
1890 C) Calibration and operation techniques shall follow the manufacturer's specifications.	1888			referei	nce materials.
manufacturer's specifications.					
1			C)		<u>.</u>
1892				manuf	acturer's specifications.
	1892				

1893		D)	Each procedure shall be recalibrated each day of use.
1894			
1895	3)	Chro	matography
1896			
1897		A)	A standard (calibrator) shall be included with each batch of
1898			unknown specimens.
1899			
1900		B)	Calibration and operation techniques shall follow the
1901			manufacturer's specifications.
1902			
1903		C)	Reference materials (spiked samples) shall be included in each
1904			batch of unknown specimens and are treated the same as
1905			unknowns.
1906			
1907	4)	Elect	rophoresis
1908			
1909		A)	The linearity of a densitometer shall be checked each day of use.
1910			
1911		B)	Reference materials for comparison of migration patterns and stain
1912			intensity shall be included with each run.
1913			•
1914	5)	Ion S	elective Electrode
1915			
1916		A)	The manufacturer's recommendations shall be followed with
1917			respect to calibration and control procedures.
1918			
1919		B)	Reference materials shall be included with each run.
1920			
1921	6)	Radio	oimmunoassay
1922	,		·
1923		A)	The stability of radioisotope counting equipment shall be checked
1924		,	each day of use with an appropriate radioactive reference source.
1925			Tolerance limits shall be established.
1926			
1927		B)	Background counts shall be performed each day of use and
1928		,	tolerance limits established.
1929			
1930		C)	Each procedure shall include calibrators (standards) as
1931		,	recommended by the reagent manufacturer.
1932			,
1933		D)	Reference materials shall be included with each run.
1934		,	
1935		E)	The duration of the counting times shall follow the
		,	5

1936				recommendations of the instrument manufacturer.
1937				
1938		7)	Mass	Spectrometry
1939				
1940			A)	Mass spectrometers shall be tuned daily.
1941				
1942			B)	Procedures for checking air leaks and determining ion ratios shall
1943				be available and followed.
1944				
1945			C)	Ion ratios shall be determined for each instrument and each assay it
1946				appropriate for the instrument.
1947				
1948			D)	If ion ranges are used, criteria shall be available for designating a
1949				positive.
1950				
1951	c)	Urina	alysis	
1952				
1953		1)	Spec	ific gravity equipment shall be calibrated with distilled water and one
1954			other	solution of known refractive index each day of use.
1955				
1956		2)	Scree	ening or qualitative chemical urinalysis shall be checked daily by use
1957			of su	itable reference materials.
1958				
1959		3)	Calib	oration and the use of reference materials for equipment which utilizes
1960		,		natic readers shall follow the recommendations of the manufacturer.
1961				
1962	d)	Bacte	eriology	r-mycology
1963	,		03	
1964		1)	Each	unit of media shall be properly labeled to indicate identity, date of
1965		,		aration-receipt and expiration date.
1966			1 1	1 1
1967		2)	Each	batch of media shall be tested before use, or concurrently with
1968		,		ted organisms, for selectivity, sterility, enrichment, and biochemical
1969				onse. A laboratory using commercially prepared microbiological
1970				re media which is quality controlled in accordance with the National
1971				mittee for Clinical Laboratory Standards (NCCLS) "Protection of
1972				ratory Workers from Infectious Disease Transmitted by Blood, Body
1973				and Tissue", need not perform quality control checks for selectivity,
1974				hment and biochemical response provided that: the laboratory has
1975				mentation which may be provided through a media label or brochure
1976				he quality control practices conform to NCCLS specifications: the
1977				atory documents receipt and condition of each batch of media to
1978				de sterility assessment by appropriate incubation and examination of
- /				are arranged assessment of appropriate incontinuous and chainmation of

1979		uninoculated media and notifies the media manufacturer of quality issues
1980		such as: cracked Petri plates, unequal filling of plates, cracked media in
1981		plates, hemolysis, freezing, excessive bubbles in media, contamination and
1982		sterility. Laboratories that prepare media for satellite laboratory locations
1983		must either perform the same quality control checks required of
1984		commercial and manufacturers (NCCLS Standards) and furnish
1985		documentation of media quality control checks to each location, or each
1986		laboratory must continue to perform media checks as currently required
1987		under 42 CFR 493.1256(e)(4)42 CFR 405.1317 (b)(1)(1988). This
1988		exception does not apply to Campylobacter agar, chocolate agar, media for
1989		the selective isolation of pathogenic Neisseria, Mueller Hinton media and
1990		media used for the isolation of parasites, virus, mycoplasmas and
1991		Chlamydia.
1992		Cinding dia.
1993	3)	Appropriate ATCC strains shall be available and maintained.
1994	3)	rippropriate rife o strains shair of available and maintained.
1995	4)	All reagents, strips, discs, and antisera shall be properly labeled as to lot
1996	•/	number and expiration date and checked each day of testing with
1997		organisms that produce positive and negative reactions.
1998		organisms that produce positive and negative reactions.
1999	5)	An adequate incubation system shall be used and shallmust be appropriate
2000	3)	for the kinds of organisms isolated and volume of work. CO2 incubators
2001		shall be checked daily to insure that CO ₂ concentration is maintained
2002		within established tolerance limits.
2003		within established tolerance limits.
2004	6)	Flow charts may be used to indicate all steps to be employed to isolate and
2005	0)	identify all organisms.
2006		dentity an organisms.
2007	7)	The daily log or worksheet shall reflect all tests and test results which lead
2008	,,	to the isolation and identification of all microorganisms.
2009		to the isolation and identification of an interconguinsmis.
2010	8)	Staining materials shall be checked each day of use against organisms
2011	0)	with the expected staining characteristics.
2012		with the expected staining characteristics.
2012	9)	A wire loop used for quantitative tests shall be calibrated prior to placing
2014	7)	into use and quarterly thereafter.
2015		into use and quarterly dieseaster.
2016	10)	Agar Disc Diffusion methods:
2017	10)	
2017		A) The agar disc diffusion test shall be checked with each new batch
2019		of media and at least once each seven days with stock cultures of
2020		Escherichia coli ATCC 25922, Staphylococcus aureus ATCC
		/ 1 /

2021

25923, and Pseudomonas aeruginosa ATCC 27853. Zone sizes

2022				shall be recorded for each antimicrobial agent. Limits shall be
2023				established.
2024				
2025			B)	Petri dishes used shall have a diameter not less than 150 mm and
2026				contain no more than 12 discs.
2027				
2028			C)	Susceptibility tests shall be performed on pure cultures only.
2029				
2030			D)	A barium sulfate turbidity standard shall be used for the Kirby-
2031				Bauer method.
2032				
2033		11)	Minin	num Inhibitory Concentration (MIC) Methods:
2034				
2035			A)	The MIC test shall must be checked with each new batch of media
2036				and at least once each seven days with stock cultures of
2037				Escherichia coli ATCC 25922, Staphylococcus aureus ATCC
2038				29213, and Pseudomonas aeruginosa ATCC 27853. The MIC
2039				values shallmust be recorded for each antimicrobial agent.
2040				Tolerance limits shall be established.
2041				
2042			B)	When trimethoprim-sulfamethoxazole is included in the battery of
2043			,	antibiotics, Streptococcus faecalis ATCC 29212 shall also be
2044				included as a control.
2045				
2046		12)	Autor	nated <u>susceptibility</u> susceptability testing systems shall follow the
2047		/		y control requirements specified by the manufacturer or at a
2048				num those specified under item 11 above.
2049				
2050	e)	Parasi	tology	
2051	• ,	1 011 013		
2052		1)	A cali	brated ocular micrometer shall be available for determining the size
2053		-/		a and parasites when size is a critical factor.
2054			01 0 1	t and parasites when size is a critical factor.
2055		2)	The la	aboratory shall have an atlas and and or reference collection of
2056		2)		red slides, transparencies or gross specimens. The collection shall
2057				le organisms which the laboratory encounters and reports from
2058				t specimens.
2059			patien	t specimens.
2060		3)	Perms	anent stains shall be used for the examination of intestinal intestional
2061		3)		too and other parasites where internal structure is critical for proper
2062				fication.
2063			idelitt	iiQuiiOii.
2063 2064		4)	Conce	entration methods shall be routinely employed on all stool specimens
∠∪∪ 1		7)	Conce	and an on memous shan be rounnery employed on an stool specimens

2066
2067
2068
2069
2070
2071
2072
2073
2074
2075
2076
2077
2078
2079
2080
2081
2082
2083
2084
2085
2086
2087
2088
2089
2090
2091
2092
2093
2094
2095
2096
2097
2098
2099
2100
2101
2102
2103
2104
2105
2106
2107

2065

negative for ova and parasites by direct examination methods. Concentration techniques shall be capable of detecting all cases of clinically significant parasites likely to be encountered in the community.

f) Immunology-Serology-Immunochemistry
Kits purchased for serological testing shall be used in accordance with the manufacturer's instructions.

1) VDRL/RPR

- A) Non-reactive, minimally reactive, and reactive reference materials shall be included with each run.
- B) The needle delivery shall be verified within plus or minus two drops per ml each time a new needle is used, when control patterns cannot be reproduced, and when the antigen does not drop clearly from the needle.
- C) The revolutions per minute of the rotator shall be checked each week of use and be within the recommended tolerance limits.
- D) Each new lot of antigen and reference materials shall be checked with non-reactive, weakly reactive and reactive reference materials before being placed into use.
- E) Ambient temperature in the test area shall be maintained between 23 degrees Centigrade and 29 degrees Centigrade.
- F) The antigen for VDRL testing shall be prepared fresh each day of use.

2) Qualitative tests

Positive and negative controls shall be included in each run. Each new lot of reagents and reference materials shall be parallel checked with one of known reactivity before being placed into use.

3) Ouantitative tests

Each quantitative test shall include with each run a negative control, where applicable, a positive control of known titer or controls of graded reactivity. Each new lot of reagents and reference materials shall be parallel checked with one of unknown reactivity before being placed into use.

2108	g)	Immu	nohematology
2109 2110 2111 2112		1)	ABO grouping reagents and Rh typing sera shall conform to the requirements of licensure under 21 CFR 600-680. Any facility which produces their own products shall adhere to these same requirements.
2113 2114 2115		2)	All antisera, ABO reagent red cells, anti-human globulin (Coombs) shall be tested each day of use with a positive control.
2116 2117 2118		3)	Antibody screening reagent red cells shall be tested each day of use with at least one known antibody.
2119 2120 2121		4)	All antisera except ABO antisera shall be tested each day of use with a negative control.
2122 2123 2124		5)	The reagent manufacturer's protocol for testing shall be followed.
2125 2126 2127		6)	An autologous cell control is required when samples are being tested for Rh type. An autologous cell control is not required to accompany the Rh type when testing donor samples.
2128 2129	h)	Histop	pathology
2130 2131 2132		1)	All special stains shall be controlled by use of positive tissues.
2133 2134		2)	All tissue specimens shall be kept in a preservative until microscopic examination and diagnosis have been completed by the pathologist.
2135 2136 2137		3)	All stains shall be filtered prior to each day of use.
2138 2139		4)	All tissue processing solutions shall be changed or rotated on a regularly scheduled basis.
2140 2141 2142		5)	The quality of stains shall be evaluated daily by the director and suboptimal stains corrected immediately.
2143 2144 2145 2146		6)	All gross tissue specimens received <u>shall</u> must be properly labeled and securely packaged so as to maintain absolute certainty of identification throughout processing, recording and storage.
2147 2148 2149 2150		7)	Slides <u>shall</u> must be identified with permanent labels and stored so they are readily accessible. Paraffin blocks <u>shall</u> must be adequately identified, indexed, stored in a cool place and protected against damage by heat for a

					0 011117 7 0 10 0 20 00 0 7 0 10 2
2151					Wet tissue specimens shall be retained until a diagnosis has
2152			been 1	nade. T	he slide and a copy of the report shall must be filed for at
2153			least 1	10 years	
2154					
2155		8)	The la	aborator	y shall request that the tissue request shall contain the name,
2156			birthd	ate, nan	ne of the surgeon, clinical information and the date of
2157			surge	ry.	
2158					
2159	i)	Cytog	genetics		
2160					
2161		1)	Specia	al Equip	oment
2162			-		
2163			A)	Incub	ators shallmust be on special emergency lines.
2164			ŕ		
2165			B)	Lamir	nar Flow Hoods <u>shall</u> must be used (Class II) .
2166			,		<u> </u>
2167			C)	Karyo	typing facilities shall must be available with the production
2168			ŕ	of har	d copies.
2169					•
2170		2)	Cultu	re Initia	tion of Specimens
2171		ŕ			•
2172			A)	At lea	st two (2) containers for each patient
2173			,		. ,
2174			B)	Maxir	num of 1% patient failure (i.e. failure to provide a report as
2175			,		ed in Section 450.1150(j)(3)), for blood, amniotic fluid and
2176					onic villus samples in a period not to exceed 30 calendar
2177				days.	If in excess of 1%, the laboratory director shallmust contact
2178				•	epartment and stop performing the tests until the laboratory
2179					emonstrate a patient failure rate of less than one percent.
2180					
2181			C)	For ot	her tissues higher patient failure rates are acceptable.
2182			ĺ		
2183				i)	Skin and products of conceptions: maximum of 20%
2184				ĺ	failure in a period not to exceed 30 calendar days. If in
2185					excess of 20%, the laboratory director shallmust contact the
2186					Department and stop performing the tests until corrective
2187					action is demonstrated.
2188					
2189				ii)	Bone Marrow: maximum of 5-10% failure in a period not
2190				,	to exceed 30 calendar days. If in excess of 5-10%, the
2191					laboratory director shallmust contact the Department and
2192					stop performing the tests until corrective action is
2193					demonstrated.

2194								
2195	3)	Anal	ysis and	Interpretation				
2196								
2197		A)	Coun	ting Chromosomes				
2198								
2199			i)	At least 11-20 metaphases from the two containers				
2200				shallmust be counted for routine blood, amniotic fluid,				
2201				skin, products of conception, and chorionic villus				
2202				specimens.				
2203								
2204			ii)	For the Fragile-X chromosome, a minimum of 100				
2205				metaphases is required before reporting a negative result.				
2206				Control values for Fragile-X shall be maintained.				
2207								
2208			iii)	If a clinically significant hypermodal metaphase or a				
2209				structurally abnormal chromosome is detected, 20				
2210				additional cells (or 10 additional centers) in each of the two				
2211				cultures <u>shall</u> must be analyzed.				
2212								
2213			iv)	If 2 clinically significant hypomodal metaphases are				
2214				detected, repeat steps in subsection (3)(A)(iii).				
2215								
2216		B)	Kary	otypes				
2217								
2218			i)	A 400 band resolution is minimum.				
2219								
2220			ii)	At least two (2) banded karyotypes (hard copies) shall must				
2221				be prepared for routine bloods, amniotic fluids, chorionic				
2222				villus specimens, skins, and products of conception.				
2223								
2224			iii)	For bone marrows, at least 25 metaphases shall must be				
2225				photographed and analyzed. A minimum of 20 cells shall				
2226				be analyzed for the presence of the Philadelphia				
2227				chromosome and other markers for chronic myelogenous				
2228				leukemia.				
2229								
2230		C)	Repo	rting and Interpretation				
2231								
2232			i)	All reports shallmust adhere to the current International				
2233				System of Cytogenetic Nomenclature.				
2234								
2235			ii)	All abnormal findings should be accompanied by a				
2236				recommendation to consult a Geneticist.				

2231
2238
2239
2240
2241
2242
2243
2244
2245
2246
2247
2248
2249
2250
2251
2252
2253
2254
2255
2256
2257
2258
2259
2260
2261
2262
2263
2264
2265
2266
2267
2268
2268 2269
2270
2270 2271
2271
2271 2272
227122722273
227122722273
2271 2272 2273 2274
2271 2272 2273 2274 2275
2271 2272 2273 2274 2275 2276
2271 2272 2273 2274 2275 2276 2277
2271 2272 2273 2274 2275 2276

2227

- D) Documentation
 In addition to other documentation required for any laboratory,
 documentation of power failure, failure rate, contamination,
 labeling discrepancy, poor or no growth, poor slide quality,
 interpretive dilemmas, and diagnostic errors shall be maintained.
- 4) Archives
 Retention of adequate slides, films, hard copies and reports in order to reanalyze any cases challenged, shall be in accordance with the State statute of limitations.
- j) Toxicology Controlled Substances (Drugs of Abuse) Laboratories which perform tests for controlled substances shall meet all pertinent requirements of the Act and regulations. In addition, the following items shall apply to toxicology laboratories.
 - 1) The laboratory shall demonstrate proficiency as required under Section 450.720, except, the laboratory shallmust discontinue providing confirmatory testing if for two consecutive testing periods the laboratory either fails to report results for confirmatory testing or for two consecutive testing periods the laboratory fails to confirm the presence of any substance in any proficiency testing specimen or on one occasion falsely confirms and reports the presence of substancesa substance(s) not in the test specimen. Reinstatement to offer confirmatory testing shall require errorless performance in two subsequent proficiency testing surveys.
 - The director shall provide in house confirmatory testing of specimens whenever initial screening shows the presence of controlled substances. The confirmatory testing shall use different principles of chemistry and be at least as sensitive as the testing used for screening purposes. Drug screening may be performed on-site with confirmatory testing at a licensed laboratory or licensed toxicology laboratory Class II Permit as authorized under Section 2-109 of the Act, Licensed Laboratory, or Licensed Toxicology Laboratory.
 - 3) The director shall develop a written program to maintain control and accountability from receipt of specimens until results are reported. In addition to other requirements of Section 450.140, requirements for segregation of these samples from other specimens received in the laboratory and the process for checking specimens for adulteration upon receipt in the laboratory, shall be stated.

2280 2281		<u>3</u> 4)	Reports from the laboratory shall include limits of detection (LOD) for methods utilized and identify the method used to confirm positive
2282			screening results. Only specimens confirmed positive shall be reported
2283			positive for a specific drug or metabolites.
2284			F
2285		4 5)	Each analytical run of specimens shall have at least three reference
2286		_ /	specimens including: a specimen containing no drug or metabolites; a
2287			specimen with a known amount of standard at or near the threshold
2288			(cutoff), and one additional reference specimen. Documentation that
2289			currently used methodology does not allow carryover to contaminate the
2290			testing of a subject's specimen, shall be maintained. A minimum of 10
2291			percent of all test samples analyzed per batch shall be a mixture of
2292			reference specimens indicated in this subsection (j)(4)above.
2293			
2294	(Sourc	e: Am	ended at 44 Ill. Reg, effective)
2295			
2296			SUBPART M: HEALTH SCREENING
2297			
2298	Section 450.1	300 H	ealth Screening and Approved Health Screening Tests
2299			
2300	a)		alth screenings shall be conducted under a protocol approved by a
2301			ian licensed to practice medicine in all its branches that includes, but is no
2302			d to, provisions concerning disclosure of the purpose and limitations of the
2303			ting tests to test subjects, proper collection of samples, and administration
2304			s, including staffing, staff training and equipment monitoring, adequate
2305			dures for protecting the confidentiality of test subjects and test results, and
2306			priate referrals for medical attention."Health Screening" means the
2307			mance of any of the following tests for the purpose of assessing a phase of
2308		_	neral state of health of human subjects (Section 2-120(a)2-102.1 of the
2309		Act):	
2310			
2311		1)	Blood total cholesterol testing by finger stick method, and
2312			
2313		2)	Blood glucose testing by finger stick method.
2314			
2315	b)		h screening protocols in this Part shall be exempt from the provisions of
2316			ns 7-101 and 7-102 of the Act. (Section 2-120(b) of the Act) Health
2317		screen	ing activities may only be conducted by the following entities:
2318			
2319		1)	Laboratories which only perform health screenings on a not-for-profit or
2320			free-of-charge basis. Not-for-profit or free-of-charge basis means
2321			screenings performed for a fee calculated to recover the actual cost of the
2322			test material and equipment and direct labor costs, excluding any cost

2323			associated with test interpretation or other administrative costs or with no
2324			direct cost to the recipient;
2325			
2326		2)	Licensed or permitted laboratories; and
2327			
2328		3)	Licensed Hospital laboratories which are exempt from regulation under
2329			the Act and not precluded from such activities under the Hospital
2330			Licensing Act. (Section 2-102.1(a)(3) and (b) of the Act)
2331			
2332	e)	Any e	ntities which conduct more than one health screening event per calendar
2333	,		shall file established protocols with the Department in accordance with the
2334		•	sions of this Subpart. A health screening event, as used in this Section, shall
2335			any day or continuous series of days not exceeding five on which health
2336			ning activities are conducted in the same location other than the principal
2337			on of the laboratory such as a health fair. Tests listed as health screening
2338			nay be conducted at the principal location of the laboratory without the
2339			col required by this Subpart. (Section 2-102.1(a)(2) of the Act). Class III
2340			t laboratories must submit a protocol regardless of where the health
2341		-	ning is conducted.
2342			
2343	<u>c</u> d)	AGEN	NCY NOTE: Health screening tests shallshould not be used as diagnostic
2344	_ /	tests.	c <u> </u>
2345			
2346	(Source	ce: Am	ended at 44 Ill. Reg, effective)
2347	`		
2348	Section 450.1	310 P	rotocol for Conducting Health Screening
2349			
2350	a)	Any e	entity that which performs health screening shall establish a protocol for
2351		health	screening activities that which is approved by a physician licensed to
2352			ice medicine in all its branches. (Section 2-120(a) of the Act)(Section 2-
2353		-	(a)(1) of the Act)
2354			
2355	b)	The p	rotocol for conducting the health screening shall:
2356		-	
2357		1)	<u>Indicate</u> the <u>tests</u> test(s) to be conducted;
2358			
2359		2)	<u>Indicate</u> the way in which results shall be reported to the test
2360			subject, including any available oral counseling and health professional
2361			referral program;
2362			- -
2363		3)	<u>Indicate</u> how confidentiality will be maintained with provisions
2364		•	that which allow testing personnel, test subject, and test subject's
2365			representative access to the test results;

2366			
2367	4)	Inclu	deinclude a written quality control program to ensureassure accurate
2368	1)		precise test values as set by the physician signing the protocol and a
2369		-	ription of the steps to be taken if the control values fall outside
2370			otable limits as set by the physician in the written quality control
2370 2371		-	
		progr	.4111,
2372	<i>5</i> \	T., .1	delicated at the atom to a tom instance from the fellowing.
2373	5)	Inclu	deinclude the step_by_step instructions for the following:
2374			
2375		A)	Specimen specimen collection, handling, transport, storage and
2376			disposal;
2377			
2378		B)	Patient preparation;
2379			
2380		C)	Typetype and volume of specimen needed and the established
2381			rejection criteria;
2382			
2383		D)	Properproper specimen identification;
2384			
2385		E)	Properproper reagent use, such as labeling, proper lot number
2386			usage, expiration dates, and storage requirements; and
2387			
2388		F)	<u>Instrumentinstrument</u> operation and calibration in accordance with
2389		,	the manufacturer's instructions;
2390			
2391	6)	inelu	de a detailed procedure for all quantitative methodologies, to be
2392	-,		ormed at least once each twenty four hours, to determine method
2393			rity over the reportable range of valves for each analyte and
2394			ument;
2395		mstr	sinone,
2396	<u>6</u> 7)	Inclu	de include directions for the use of one reference material and one
2397	<u>u</u> ,		rator or two reference materials with different concentrations once
2398			24 hour period in which the analyzer is used;
2399		cacii	24 hour period in which the analyzer is used,
2400	<u>7</u> 8)	Inclu	deinclude a description of the training required of all staff conducting
2400 2401	<u>/</u> 6)		
2401 2402		speci	fic health screening tests;
	90)	In also	dainalude a convert advantianal materials for each individual
2403	<u>8</u> 9)		deinclude a copy of educational materials for each individual
2404		scree	ning test given to each test subject;
2405	010	D 1	9111 7 111 141 2 1 1 1 2 2 2 2 2 2
2406	<u>9</u> 10)	Repe	available to all health screening personnel at the test site;
2407	40441	D 1	
2408	<u>10</u> 11)	<u>Be</u> be	sent to the Department at least 30 days prior to the initial testing date

2409		if more than one health screening event is conducted by that entity in a
2410		calendar year. These Such protocols shall will be effective for one year. An
2411		existing protocol may be renewed by submitting to the Department a letter
2412		from the physician who signed the protocol specifying that no changes
2413		have been made in the protocol and that the protocol will be used for
2414		health screenings over the next year. This letter shall must be submitted
2415		within 30 days prior to the expiration of the existing protocol;
2416		
2417	<u>11</u> 12)	Bebe signed, dated, and approved by a physician licensed to practice
2418		medicine in all its branches no earlier than three months prior to
2419		submission date;
2420		
2421	13)	include, for not for profit or free of charge operations, a statement from
2422		the physician who signs the protocol that the education and experience of
2423		the staff members are adequate to assure proper specimen collection,
2424		specimen handling, instrument operation, quality assurance, record-
2425		keeping, reporting of results, and proper sanitary conditions to protect the
2426		test subjects and the environment;
2427		,
2428	<u>12</u> 14)	<u>Include</u> a copy of the document to be given to each test subject
2429		which discloses the purpose and limitations of each individual screening
2430		test to be conducted;
2431		
2432	15)	state whether the testing to be conducted will be done on a <i>not-for-profit</i>
2433	10)	or free-of-charge basis or for-profit basis. If the testing is conducted on a
2434		not-for-profit basis, then the calculations used to determine the actual cost
2435		of the test material and equipment must be included.
2436		or the cost manufact and equipment in the control of the cost of t
2437	<u>1316</u>)	<u>Include</u> copies of any forms used in the course of conducting
2438	<u> 15</u> 10)	health screening activities;
2439		nearth sercening dentities,
2440	14 17)	Indicateindicate how documentation and quality control items are
2441	<u></u>	traceable to each individual analyte and instruments used in the health
2442		screening process and how records shall be maintained; and
2443		sercening process and now records shall be maintained, and
2444	<u>1518</u>)	<u>Indicate</u> how records of test subject results and documentation of
2445	<u>15</u> 10)	quality control items shall be maintained for two years., and
2446		quanty control items shall be maintained for two years, and
2447	19)	document the basis for any fee charged to the recipient indicating whether
244 <i>7</i> 2448	17)	testing is being done on a for-profit or not-for-profit basis.
2446 2449		testing is being done on a for-profit of not-for-profit basis.
2449 2450	(Source: Am	ended at 44 Ill. Reg, effective)
2450 2451	(Source, Alli	chaca at 77 III. Rog, checuve
∸ T JI		

2452 Section 450.1320 Application for a Class III Permit to Conduct Health Screening 2453 (Repealed) 2454 2455 The owner of a clinical laboratory which is operated and maintained exclusively for the purpose 2456 of conducting health screening tests by a person, corporation, organization, association or 2457 group which provides health screening services in accordance with Section 2-102.1 of the Act 2458 either directly or indirectly on a for profit basis must obtain a permit from the Department. 2459 Application shall be made on a form prescribed by the Department. The application shall be accompanied by an application fee of \$200 for each such permit. The application shall be under 2460 2461 oath (i.e. signed by the owner or authorized officer and notarized), the permit shall expire each 2462 year on a date specified on the permit, and the application shall contain the following 2463 information: 2464 2465 The name and location of the owner's principal place of business; a) 2466 The name of the owner of such facility and of the director thereof; 2467 b) 2468 2469 When the owner is a corporation the names and addresses of all persons owning e) 2470 five percent or more of shares of the corporation; 2471 2472 d) a completed personnel form for the director(s), the anticipated schedule of hours 2473 for the director(s) to be at the laboratory during hours of testing, and other 2474 laboratories directed by the director(s); 2475 2476 a description of the program and services provided by such clinical laboratory; e) 2477 2478 f) The name of the laboratory assistant(s) or technician(s) employed and a 2479 completed personnel form for each laboratory assistant or technician; 2480 2481 the name of the person(s) who is in charge of the total laboratory operation at the g) 2482 test site and a personnel form(s) for that person; 2483 2484 a statement signed by the director indicating that the person in charge of the total h) 2485 laboratory operation at the test site has the education and training necessary to 2486 assure proper specimen collection, specimen handling, instrument operation, 2487 recordkeeping, reporting of results to assure confidentiality of test subjects and 2488 results, and proper sanitary conditions to protect the test subjects and 2489 environment: 2490 2491 i) an explanation of the location where all equipment and supplies are kept when not 2492 at the test site and the location where all records are kept relating to the laboratory

operations at the test sites; and

2493

2494

2495	j)	a copy of the physician approved protocol.
2496		
2497	(Source	ce: Repealed at 44 Ill. Reg, effective)
2498		
2499	Section 450.1	330 Reporting and Notification
2500		
2501	a)	All health screening entities shall file a protocol with the Department in
2502		accordance with Subpart M-of this Part.
2503		
2504	b)	All health screening entities shall notify the Department of all health screening
2505		sites, including street address, city, zip code and any other identifying data that
2506		are available, at least seven days prior to any health screening event.
2507		
2508	c)	All health screening entities shall notify the Department of all personnel
2509		anticipated to conduct any health screening event-including name, professions,
2510		training background, street address, city, zip code at least seven days prior to any
2511		health screening event.
2512		
2513	(Source	ce: Amended at 44 Ill. Reg, effective)
2514		

Section 450.APPENDIX C Exempt, Permit, and License Requirements – An Overview (Repealed)

	EXEMPT	CLASS I PERMIT	CLASS II PERMIT	CLASS-III PERMIT	HEALTH SCREENING (PROTOCOL)	LICENSE
ELIGIBILITY CRITERIA	Single practice medicine, podiatry, dentistry or local health authority or designated agency Single practice medicine includes: M.D.s, D.O.s D.C.s [See Section 450.5(b)(1)]	Single practice medicine, podiatry, dentistry or local health authority or designated agency Single practice medicine includes: M.D.s, D.O.s D.C.s [See Section 450.5(b)(2)]	Owner where lab operated exclusively for patients of physicians, podiatrists, or dentists who own or are employed by the owner or local health authority or designated agency or Class I [See Section 450.5(b)(3)]	Owner where lab operated exclusively for health screening for-profit basis either directly or indirectly [See Section 450.5(b)(4)]	Any laboratory [See Section 450.1300(b)]	Owner to operate lab to accept specimens from any persons authorized to submit such specimens [See Section 450.5(b)(5)]
DIRECTOR	None	M.D., D.O., D.D.S., D.P.M., D.C., Ph.D., M.S., or Grandfathered who meets regulations [See Section 450.210(b)(1)]	M.D., D.O., Ph.D., M.S., or Grandfathered who meets regulations [See Section 450.210(b)(2)]	M.D., D.O., Ph.D., M.S., or Grandfathered who meets regulations [See Section 450.210(b)(3)]	Non-profit testing no requirements except a protocol For-profit testing Class-III-permit	M.D., D.O., Ph.D., M.S., or Grandfathered who meets regulations [See Section 450.210(b)(4)]
PERSONNEL OTHER THAN DIRECTOR (Minimum)	None	Laboratory assistant, if any [See Section 450.210(b)(1)]	Technician or Technologist [See Section 450.210(b)(2)]	Technician or Laboratory Assistant [See Section 450.210(b)(3)]	None	General supervisor (if director not present full time) [See Section 450.210(b)(4)
FEES	None	Annual Initial \$50 Renewal \$25	Annual Initial \$100 Renewal \$50	Annual Initial \$200 Renewal \$100	None	Annual Initial \$300 Renewal \$150
INSPECTION FREQUENCY	No mandated inspection	No mandated inspection	At least every 2½ years	At least every 2 years	No mandated inspection	At least annually
PROFICIENCY TESTING	None	Required for tests offered [See Section 450.720]	Required for tests offered [See Section 450.720]	Required for tests offered [See Section 450.720]	None	Required for tests offered [See Section 450.720]
TEST PERMISSIBLE	List of minor tests [See Section 450.35(a)]	Minor and simple tests [See Section 450.35(b)]	Minor, simple and complex test [See Section 450.35(c)]	Cholesterol and glucose [See Sections 450.35(d) and 450.1300(a)]	Cholesterol and glucose [See Section 450.1300]	Any test as long as Director qualifies [See Section 450.35(e)]

I	CAR	77∩∠	150	-200	າຊດ	173	ŀr∩	n
J	$C \cap I \cap I$, , 0-	もりひ	-201	JJU	נוי	עני	_

2519 (Source: Repealed at 44 Ill. Reg. _____, effective _____)